

2080. CONTRACTS BETWEEN STATE AGENCIES AND FISCAL AGENTS, HEALTH CARE PROJECT GRANT CENTERS, PRIVATE NONMEDICAL INSTITUTIONS, HEALTH INSURING ORGANIZATIONS, HEALTH MAINTENANCE ORGANIZATIONS, PREPAID HEALTH PLANS AND FOR CONTRACTS FOR AUTOMATIC DATA PROCESSING EQUIPMENT/SERVICES

2080.1 Applicable Federal Regulations.--The general regulations applicable to all Medicaid contracts and subcontracts involving the various State Agencies (SA) and Fiscal Agents (FA), Health Care Project Grant Centers (HCPGC), Private Nonmedical Institutions (PNI), Health Insuring Organizations (HIO), Health Maintenance Organizations (HMO), and Prepaid Health Plans (PHP) are in 42 Code of Federal Regulations (CFR) 434, CONTRACTS. The general regulations applicable to contracts for automatic data processing (ADP) equipment and services are in 45 CFR 95, Subpart F. SA procurement contracting procedures for contracting are subject to other regulations including 45 CFR 74, Subpart P, and Appendix G (Procurement Standards) to this regulation.

Each of these regulations must also be considered in light of Federal financial participation (FFP) requirements in 42 CFR 433, Subpart A, applicable to general Federal matching provisions and those involving more specific conditions for FFP in the acquisition of mechanized claims processing and information retrieval systems in 42 CFR 433, Subpart C.

2080.2 Prior Approval Requirements.--As noted in §2080.1, SA contracts are subject to the regulations at 45 CFR, Part 74. Those regulations allow you to enter into contracts without prior Federal approval. There are two (2) general exceptions. The first applies to contracts for ADP equipment and services; 45 CFR 95.611 requires that you obtain prior written approval from the Department of Health and Human Services (HHS) for any ADP equipment or services where the total estimated Federal and State funding for the acquisition equals (a) \$200,000 or more over a twelve (12) month period, (b) \$300,000 or more for the total acquisition, or (c) \$25,000 or more where the equipment/services are acquired noncompetitively. This requirement applies not only to procurement of ADP equipment and services but particularly to procurement of FAs whose primary function is to provide mechanized claims processing and information retrieval systems and/or the ADP services required to operate such systems.

The second exception applies to contracts for the design, development, installation and/or improvement of Medicaid Management Information Systems (MMIS) where enhanced funding at the 90 percent rate is requested. 42 CFR 433.112 and Part 11 of the State Medicaid Manual (SMM) requires you to obtain, prior to your expenditure of funds for the project, written approval from the HCFA of any Advance Planning Document (APD) involving a request for 90 percent FFP regardless of funding amount.

While all requests for prior approval are submitted to the Assistant Secretary for Management and Budget (ASMB), HHS, those requests which involve only title XIX funding are submitted simultaneously to the appropriate servicing regional office (RO), and directed to the attention of the Associate Regional Administrator for Financial Operations (ARAFO). The documents submitted are dependent upon the developmental stage of the request and include: the APD, the Request for Proposals (RFP), the Detailed Implementation Plan (DIP), Proposal Evaluation Plan (PEP), final contending proposals, the proposed contract, and contract amendments and extensions.

2080.3 Provide That All Contracts Are In Writing.--The regulations give you a great deal of latitude regarding the scope and form of contracts with the designated types of contractors. However, a written instrument is required. HCFA has samples of contracts and agreements between the SAs and relevant contractors which are available to you upon request to provide guidance on general format and content. The contract samples are for guidance only and should not be construed as approved HCFA policy regarding any particular phraseology used.

2080.4 Specify the Contract Period.--Contracts should be for a defined length of time. The cost of contracting for both the bidders and you suggests that the contract should serve both parties for more than a single year. Conversely, contracts should not be permitted to continue indefinitely without being recompeted. In FA service type contracts, HCFA recommends that, where possible, you consider entering into contracts with an initial duration of up to five (5) years but contracts should not exceed eight (8) years including separate optional renewals. HCFA recognizes that procurement requirements in some States prohibit contracting for more than a specified period for varied reasons, including State budgetary limitations. You are encouraged to enter into contracts for periods consistent with your State requirements and the Federal competitive procurement requirement, 45 CFR 74, Appendix G, 10a. This could be accomplished by contracting for an initial term to conform with the State regulation but also provide for a limited number of optional renewal terms to a maximum contract term of eight (8) years inclusive. Specify in contracts involving FAs that the conditions are firm and fixed during the life of the contract and specify the pricing and conditions for changing the contract. A clause permitting cancellation within a specified period of time if the contractor is found to be not in compliance with the contract's terms must be included.

2080.5 Specify the Functions of the Contractor.--The contract should be precise about the obligations of the contractor and you to avoid ambiguities, particularly in such areas as nonperformance, payment or other sensitive matters where the possibility of dispute exists. The contract must contain both a list of functions and a definition of the scope of each. The exact functions depend upon the type of contract involved (claims processing, insurance, direct delivery) and upon which functions contractors will perform and which you will perform.

2080.6 Identify the Population Covered by the Contract.--Contracts for all types of contractors must specify the covered population. The FA contracts and other contracts that require only administrative functions will comply with this regulation if they state the eligibility classes of recipients for which claims are processed and the geographic areas of the State from which claims will be accepted. Contracts for health coverage of specific individuals, whether on an insurance or direct-delivery basis, must be specific as to market area, class of eligibles, limitations, and enrollment procedures. Identify market areas in terms of distinct physical or political boundaries. Define the covered population both in terms of eligibility characteristics, such as all Medicaid or Aid For Dependent Children only, and in terms of the population characteristics necessary to compute an actuarially-based rate. These definitions are required whether or not the contractor is at risk for part or all of the services.

2080.7 Specify the Procedures for Enrollment or Reenrollment of the Covered Population.--The requirement for specifying enrollment/reenrollment procedures does not, of course, apply to FAs. All other contractors must specify the nature of their enrollment procedures. These include, as a minimum, a description of marketing approach, the period of enrollment, reasons for involuntary cancellation of enrollment and refusal to enroll or reenroll (e.g., preexisting conditions or maximum use of services) and the period of open enrollment, if limited. (See 42 CFR 431.511-431.590 for special HMO and Health Care Prepayment Plans enrollment, disenrollment and population served requirements.)

2080.8 Specify the Amount, Duration and Scope of Medical Assistance to be Provided or Paid for.--Define in detail the range of services provided or paid for, the period for which the services will be provided, if different from the contract period, and any limits on dollar or other amounts of services. If a contract is to exclude some benefits provided in the State plan, define these exclusions and the procedures by which recipients obtain these services (e.g., exclusion of long-term care benefits from a prepaid contract might be desirable, but if this is done the SA must give assurance that enrollees have access to this service through other means).

2080.9 Provide for Evaluation of Services Performed and for Audit and Inspection of Contractor Records.--Inspections for quality, appropriateness and timeliness of services must be in the form of systems tests, assessments, performance reviews, on-site audits, and regular reports from the contractor. The SA is responsible for establishing and maintaining a contract administration process to insure that the contractor's performance is in accordance with the terms, conditions and specifications of the contract per 45 CFR 74 (paragraph I5, appendix G). Be prepared to define to the contractor your inspection and audit procedures in the specified areas at the time the contract is negotiated, but the contract must clearly state also that there shall be no restrictions on the right of the SA or HHS to conduct whatever inspections and audits are necessary to assure quality, appropriateness or timeliness of services and reasonableness of their cost.

2080.10 Specify the Procedures and Criteria for Extending the Contract.--Delineate the reasons for granting extensions and the procedures to be followed. Generally, extensions beyond the basic contract term or optional periods are the exception and not the rule. Extensions in time should be for a defined, fairly short length of time, and not permit changes in the basic conditions of service or coverage. For example, an extension for a limited period would be appropriate to permit an incumbent FA to continue to perform its functions while the new contractor is phasing in its operations.

Minor rate changes during extensions are permitted if justified, but should not be encouraged since they tend to foster perpetuation of old contracts. Renegotiations or extensions must be approved by the ARA, DFO, if the total increase exceeds \$100,000 for other than ADP equipment or services. If the contract involves the acquisition of ADP equipment or services, the approval requirements of 45 CFR 95 Subpart F apply.

2080.11 Specify Renegotiation Procedures and Criteria.--Make provision for renegotiation for good cause only at the end of the contract period and for modification(s) during the contract period if circumstances warrant. Define in detail the grounds for renegotiating a contract in detail and limit them in scope. Do not use renegotiation as a means to avoid recompeting the contract. It is desirable to require that renewal negotiations begin several months in advance of the contract's expiration to avoid deadline complications. Procedures for renewal negotiation may be the same as those for initial negotiation, except that additional experience data are available to use in setting the new terms. Permit modifications during the contract period only for a set of well-defined conditions. Reasons for modification could include a change in scope of services or service area, adjustment of rates, changes in terms and amount of payment and alteration of subcontract arrangements. If the need for modification is for ADP services, an APD should be submitted concurrently to the ASMB and the appropriate HCFA RO (attention: ARA, DFO) for approval.

2080.12 Specify Procedures and Criteria for Termination and Include a Requirement to Supply All Information Necessary for Reimbursement of Outstanding Medicaid Claims.--Termination of contracts, either voluntarily or involuntarily, presents the most difficult contractual problems. Give paramount consideration to assuring that eligible recipients continue to have access to services under the State plan and that all outstanding claims of providers and participants are settled promptly, as specified in 42 CFR 431.503(i)(3). This requires that the contractor maintain and provide information necessary to determine such claims and to determine which eligibles or enrollees must be picked up by some other program. Require capitated risk contractors to establish a cash reserve to assure that, in the event of insolvency, outstanding claims can be satisfied.

2080.13 Contractor Must Maintain Appropriate Record System for Services to Enrolled Recipient.--The type of service record system to be kept depends upon the type of contract involved. A fiscal agent's (FA) contract must specify a record system that records each individual service rendered and its cost. It is desirable that such a system meet the requirements of MMIS or other nationally recognized reporting procedure. In general, an FA record system is claim-based.

The record system for a contractor providing direct delivery of care on a nonrisk basis may be claim-based, recording each individual service as it is provided, or it may be aggregated. In all cases, however, the system must be capable of demonstrating that payments to the contractor did not exceed allowable amounts and that services for which payments were made were provided. This capability may be demonstrated on a sample basis.

Contracts with organizations assuming an underwriting risk need not require service-by-service records, since this defeats part of the cost saving potential of risk contracting. The main focus of a record system for risk contractors is to assure that mandated services are provided and that they are of acceptable quality. The records must allow the organization to monitor this on a regular basis and the State to monitor on a scheduled periodic basis. Again, a sampling procedure may be employed to demonstrate this capability.

In all cases, the record system must provide data in an accurate and current form useful to Federal and State program agencies monitoring and managing the program. Develop a comprehensive reporting system that includes data useful for monitoring program performance in areas such as quality and accessibility, as well as completion of services.

2080.14 Retain Records in Accordance With Requirements of 45 CFR Part 74.--The general record retention requirement of three years is in Appendix G, paragraph 14.h of 45 CFR, Part 74, originally issued as Office of Management and Budget (OMB) Circular A-102, Attachment O. This paragraph refers to 45 CFR 74.164 for clarification of the record retention requirements pertaining to both contracts and subcontracts involving HHS grants and subgrants. That section requires a retention period of three years after final payment is made and all pending matters are closed, plus an additional period if an audit, litigation, or other legal action involving the records is started before or during the original three-year period.

2080.15 Provide for Safeguarding Information About Recipients.--Information about recipient, applicant, and provider eligibility under title XIX or the amount of assistance and services provided is confidential. However, information can be made available for purposes directly connected with administration of the program. Clear requests for use of confidential Medicaid data through appropriate SA personnel. Contractors are expected to exercise prudent judgment when they receive requests for information.

2080.16 Specify Contractor Activity Related to Third Party Liability Requirements.--The regulations require the State agencies (SAs) to coordinate benefits so that its payments to title XIX recipients are reduced to the extent that any third party coverage maintained by or for recipients pays for part of the service. (See 42 CFR 433.135 ff.) Specify how this is to be done by the contractor and the SA, for example, by:

- o Requiring that the contractor determines the degree of third party coverage, collects this payment when appropriate, and reimburses the State on a regular basis;
- o Having the SA make this determination and recover directly from the third party;
- o Having the contractor deny payment on claims for which a third party has been determined to be responsible; or
- o Using experiential data to estimate the dollar amount of third party recovery, deducting this from the amount paid to the contractor, and permitting the contractor to retain whatever it can recover. This establishes a financial incentive for recovery of third party payments but requires good estimating data and techniques.

Regardless of the method selected for verifying and collecting from third parties, the SA or its delegated local governmental unit attempts to ascertain whether eligibles carry third party coverage at the time eligibility is verified. Report this to any contractor which enrolls such a person, and update the information whenever eligibility is redetermined. In addition, require FA contractors to check their own eligibility files for information on whether the recipient has private health insurance. Federal matching funds are not available for Medicaid payments when the SA has not exhausted its means of recovering from the responsible third party.

Note that health maintenance organizations (HMOs) and/or competitive medical plans (CMPs) are responsible for maintaining records in such a manner as to assure that all monies collected from third party resources may be identified on behalf of Medical assistance recipients. The HMO/CMP makes these records available for audit and review and certifies that all third party collections from all groups covered by these plans are identified and used as a source of revenue for rate setting purposes.

2080.17 Specify Functions to Be Subcontracted.--Spell out clearly the various types of obligations which can be assigned to subcontractors. The regulations impose basically the same requirements for subcontracts as those for the prime contract. (See 42 CFR 431.504.) Affix a copy of anticipated subcontracts to the prime contract.

2080.18 State Contracts With Outside Parties to Verify for Providers a Medicaid Recipient's Eligibility.--Private firms, other than your FAs, may use Medicaid recipient data to respond to provider queries regarding Medicaid eligibility. There have been several changes in technology, in the providers' needs, and in the increasing number of various outside parties (agents of the State) entering the eligibility verification arena.

A. Guidelines for State Contracts With Outside Parties to Verify Medicaid Recipient's Eligibility.--These guidelines define the conditions under which eligibility data may be released to providers. Review the following before you contract with outside parties for Medicaid eligibility verification:

- o Any outside party that is permitted to furnish eligibility information must be an agent of the State and must enter into a contract with the State.

- o You must have available for your servicing regional office, if requested, a copy of each contract you have with outside parties to verify Medicaid recipients' eligibility.

- o An agent of the State who disseminates eligibility verification information (e.g. a switch) cannot bill on behalf of the providers in that State unless it meets the requirements stated in subsection E.3. A switch is an entity that may receive and transmit eligibility information as defined in subsection E.3.

- o Agents of the State must agree in writing not to use the information furnished to them for any purposes other than to give Medicaid providers eligibility information (e.g., mailing lists cannot be sold or used for any reason). The eligibility information may be given only as a direct result of a provider inquiry on a specific individual.

- o The agent may furnish eligibility data to providers duly enrolled in the State's title XIX program or other State-operated programs that provide medical services and rely on Medicaid eligibility as a condition for assistance under those programs.

- o The agent's service must be available to any interested Medicaid provider.

- o Only eligibility information for dates within 12 months of the date of query may be furnished to providers.

- o The fees charged to providers, if any, must be reasonable.

- o The contract must specify that the agent must adhere to relevant confidentiality/privacy laws, regulations, and contractual provisions and that the agent must establish appropriate administrative, technical, and physical safeguards to insure the security and confidentiality of records.

- o The contract must specify that the agent must maintain records for 1 year showing provider name, recipient name, provider identification number (which can be cross-referenced to a Medicaid certification number), the number of inquiries for each provider, the dates of the provider queries, and the dates the services were rendered.

- o The contract must specify that the agent is subject to random auditing by you and that upon confirmation of contract violations, you may require appropriate corrective action and/or terminate access to the data, depending upon the nature and degree of the violations.

- o You are urged not to enter into more than three contracts with outside firms to provide this service. If you propose to enter into more than three contracts to provide this service, first obtain the approval of your servicing regional office.

B. Data the State May Release to Its Agents or Providers.--

1. To the Agent.--Release only information needed to perform the limited function in the administration of the Medicaid program covered by the contract. Only Parts A and B of Medicare eligibility status may be released from the Benefit and Earnings Data Exchange (BENDEX). Do not release the entire BENDEX benefit tape to an agent under any circumstance. See subsection 2 for a list of information that can be released to an agent.

2. To the Provider.--Your agent is prohibited from releasing the entire Medicaid eligibility tape to a provider. Only the following information may be given to providers:

- o Recipient name;
- o Recipient medical assistance identification number;
- o Recipient Medicare health insurance claim number (HICN) (see subsection C.);
- o Social security number (if, upon signing the application for assistance, an individual agreed to the release of certain information for purposes directly related to plan administration, e.g., release of social security number to verify income, eligibility, and benefit amounts. If an individual has not agreed to the release of personal information, i.e., the application for assistance did not contain a statement to this effect nor was there a personal privacy protection law notification provided at the time of application, the social security number may not be released to the provider until permission is obtained (from the individual) in the form of a signed document.);
- o Date of birth;
- o Indication that the individual is eligible for the date queried or a range of dates queried (records reporting all periods of eligibility are not allowable);
- o The scope of services for which the recipient is eligible;
- o Third party insurers, including policy number and type of coverage;
- o Service prior authorization requirements;
- o Copay amounts to be satisfied;
- o Lock-in/lockout restrictions on the recipient record;
- o Unit or dollar limits and the portions/amounts used;
- o Capitation plan enrollments, i.e., enrollments of recipients in HMOs or health insurance organizations (HIOs) which are not third party insurers. You may release names, addresses, and telephone numbers of HMOs and HIOs which have primary responsibility for the enrollee/recipient. (Enrollees have the option of joining fee for service, HMOs, or other HIOs.); and
- o Names and telephone numbers of primary care physicians or case managers if the recipient is in a primary care case management plan (fee for service type).

C. Accessing the Data.--Providers may access the Medicaid eligibility information only by entering the recipient's Medicaid identification number or two or more of the following data elements:

- o Recipient's full name, including middle initial;
- o Recipient's date of birth;
- o Recipient's social security number;

AND by entering date(s) of service(s). If a span of service dates is entered, you determine the length of the span that is appropriate, not to exceed a maximum of 12 months prior to the query date. If a specific date of service is requested, the date cannot be more than 12 months prior to the query date.

NOTE: The above rule for accessing two or more data elements does not apply when a State magnetic stripe card containing a unique Medicaid recipient identification number is used to access the system.

Medicare certified institutional providers, as defined in §1861(U) of the Act, are allowed automated access to beneficiary eligibility data. Release of that data to providers includes the Medicare beneficiary's HICN and must be for the purpose of verifying a patient's eligibility for benefits under the Medicare program.

Consistent with the Medicare program, access by the Medicaid providers to a recipient's Medicare HICN under the Medicaid program may be permitted if the use or disclosure of that information is for purposes directly connected with administration of the State plan. Those purposes include information necessary for a Medicaid provider to know for which services Medicaid pays, and the extent to which the provider must bill Medicare or other third parties before billing Medicaid. Medicaid disseminates information available on services that are covered for a specific individual and indicates if that individual has Medicare or other third party coverage.

D. Confidentiality of Data.--Your contract with the agent must show the agent agrees to adhere to relevant confidentiality/privacy laws, regulations, and contractual provisions. Your agent must be subject to standards of confidentiality comparable to those of your agency. (See 42 CFR 431.306(b).) This is in addition to the requirement that restricts the use or disclosure of information to purposes directly connected with the administration of the State plan. (See 42 CFR 431.301.)

Your agent must establish appropriate administrative, technical, and physical safeguards to insure the security and confidentiality of records.

Release of Medicaid eligibility data to your agent in order for the agent to redisclose it to providers is permissible since the release of the data is directly related to plan administration.

State plans must provide, under State statutes which impose legal sanctions, safeguards against impermissible disclosure of information concerning Medicaid recipients. These sanctions must apply to all individuals with access to the

data. The contract must specify that the agent will be subject to random auditing by you and that, upon confirmation of contract violations, you may require appropriate corrective action and/or terminate access to the data, depending on the nature and degree of the violations.

E. Definitions.--The definitions below concern the kinds of entities, i.e., outside parties, that are involved from time to time in the activities covered in this section of the SMM.

1. Billing Agent or Business Agent.--A billing agent is an individual or organization that furnishes statements or bills and receives payments in the name of the provider. The billing agent receives compensation for services that are related to the cost of processing the billing, but the compensation is neither related to a percentage or other basis for the amount that is billed or collected nor is it dependent upon collection of the payment. Billing agents cannot bill on behalf of providers in a State and also disseminate eligibility verification information in that State. (See 42 CFR 447.10(f).)

2. Collection Agent or Factor.--A collection agent or factor is an individual or organization that advances money to a provider for accounts receivable that the provider has assigned, sold, or transferred to the collection agent for an added fee or a deduction of the portion of the accounts receivable. Collection agents cannot participate in or receive payment under the Medicaid program. (See 42 CFR 447.10(b).)

3. Switch or (Switching Companies).--A switch is an entity which uses telecommunications to act as a conduit or pass-through of eligibility verification data to facilitate a provider's access to that data. The function of a switch is limited to acting as a conduit of real time on-line transaction data by receiving eligibility verification data and transmitting that data to providers, without altering or retaining any of that data en route. A switch may serve as a billing agent for providers only if it meets the requirements for both the switch and billing agent functions and ensures that both of those functions are maintained as separate and distinct operations.

2081. SUBCONTRACTS

2081.1 Subcontracts Must Be in Writing and Comply With Pertinent General Requirements for Contracting (see §2080).--All subcontracts must be in writing with the subcontractor's functions and duties clearly identified. Each subcontract must conform to the appropriate provisions of §2080.17 as though it were a prime contract. This includes the requirement for prior approval of contract amounts. (See §2080.2.) Require SA review and approval of all subcontracts prior to their taking effect, and subject all

subcontractors to the same type of review given the prime contractor. It is strongly urged that the SA require every contractor to deliver the basic "core" services within its own organization, since excessive subcontracting can separate control from responsibility and lead to quality of service problems, among others. Obviously, the degree to which services can be provided internally rather than by subcontract depends on the size of the contractor and on the type of organization. For example, an HMO which contracts with a professional organization of physicians to provide basic medical services to enrollees is acceptable.

2081.2 Subcontracts Must Not Terminate Contractor's Legal Responsibility for Overall Performance Under the Contract.--No subcontract, no matter what the terms, can relieve a prime contractor of its sole responsibility to the SA to assure that all functions are performed and all terms of the contract are met. Adherence to this requirement is simplified if allowable subcontracting activity is limited to ancillary services.

2082. SPECIFIC REQUIREMENTS FOR FISCAL AGENT CONTRACTS

2082.1 Include Certain Termination Procedures.--In addition to the applicable requirements for contracting and subcontracting (See §2080 and §2081), FA contracts must include termination procedures that require the contractors to supply promptly all material necessary for the continued operation of payment and related systems. This material includes computer programs, data files, user and operation manuals, system and program documentation, and other necessary documentation and training programs for use by Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system.

The State has a right to assure itself of uninterrupted claims processing capability in the event that a contract with a FA is terminated. Develop procedures to assure that the State is not locked into one contractor simply because that contractor has control of all mechanical details of the claims processing system. Such systems must be made available both to the SA and to other FA contractors that the State may select. Give consideration to the development of the State's capability to run the system, with only technical assistance by the FA, during the contract period at the State's designated ADP facility.

2082.2 Provide for Obtaining Certain Proprietary Rights to Designated Materials.--Systems developed with State or Federal funds are considered to be owned by the public, and all programs, files, manuals, system documentation, training programs and other material must be kept up to date and turned over to the SA upon request. Systems that are wholly proprietary must be available for purchase, lease or rental. Systems that are partially proprietary must be identified as to the material considered proprietary at the time the contract is negotiated and that material must be made available for purchase, lease or rental upon termination. In the event a contractor or potential contractor claims proprietary rights to a system where there is reason to believe that Government funds may have partially or completely financed its development, conduct an audit to assure the State of the validity of the contractor's claim.

2082.3 Comply with Designated Payment Requirements.--Contracts with a FA must comply with certain payment requirements. These include stating the amount to be paid to the contractor for performing its functions under the contract, the basis for the amount to be paid, when payment is to be made and that payment to providers is made in accordance with Federal regulations (See 42 CFR 447, Subpart A). Payment to FAs can be made in several ways, including flat amounts, flat amounts per claim, percentages of the projected claims volume, some combination of these two, or by any other reasonable method. Do not use cost plus percentage of cost contracts as they give FAs no incentive to control costs. Encourage incentive contracting, under which the administrative fee is made a function of some specific performance goals, should be encouraged.

2083. PROCUREMENT PROCEDURES AND POLICIES FOR STATE MEDICAID CONTRACTS

2083.1 General Statement of Intent.--This section clarifies, where possible, those provisions of the general procurement standards as they relate to specific Medicaid procurement requirements including acquisitions of ADP services performed by a FA (see 45 CFR 95 and 42 CFR 431.510), MMIS systems (see 42 CFR 433, Subpart C), pure ADP equipment and services (see 45 CFR 95) and other FA services (see 42 CFR 431.510) and the appropriate FFP provisions for each.

2083.2 Federal Procurement Policies for Grant Recipients.--In 1979 the OMB issued a revision to Attachment O of OMB Circular A-102 which liberalized the general procurement standards governing States and other local Governments receiving Federal grants and subgrants. They are now included in 45 CFR 74, Subpart P and Appendix G. The revision continues previously proclaimed general Federal policy of minimum intervention in the procurement operations of the grant recipients. Several of the more significant changes which might affect Medicaid procurements follow.

A. Judgmental Matters.--The revision prohibits Federal agencies from substituting their judgment for that of the grantee unless the matter is primarily a Federal concern. By implication, it also prohibits grantees that award subgrants from substituting their judgment for that of the subgrantee, unless the matter is primarily a concern of the grantee or the Federal Government.

B. Certification of Procurement System.--The revision creates a program for certifying a grant recipient's procurement system as meeting the standards in the regulation. If a grant recipient's procurement system is certified, awarding parties are prohibited from imposing certain prior approval requirements on the grant recipient's individual procurements.

C. Protest Review Authority.--The revision limits an awarding party's authority to review protests concerning the grant recipient's selection of a contractor. OMB has stated that this is properly the responsibility of the grant recipient.

D. Procurement Methodology.--The revised regulation describes the various methods of procurement permitted under grants and subgrants. It also requires some form of cost or price analysis in connection with every procurement action, including contract modifications.

E. Possible Conflict With Other Departmental Grant Provisions.--Despite the liberality of the language used in the revised procurement standards, if other terms of an HHS grant include provisions on procurements, those provisions also apply and take precedence over those of the revised regulation (See 45 CFR 74.4 and Federal Register, Volume 45, Number 1, Page 37666). The revised standards must, therefore, be utilized to harmonize with the various procurement requirements of the regulations referable to FA, MMIS, ADP services and equipment and FFP.

45 CFR 74, Appendix G, prohibits HCFA from imposing additional procurement requirements or subordinate regulations upon grantees unless specifically required by Federal law or executive orders, or authorized by the Administrator for Federal Procurement Policy. It also permits the States to use their procurement procedures provided that the procurements conform to the limited Federal standards enumerated in Appendix G.

The regulation thus gives the States wide latitude in the procedural aspects of the procurement process. Since 45 CFR 74 also provides for prior Federal review of proposed contracts only in certain limited circumstances, compliance is normally monitored primarily through audit or other after-the-fact reviews. However, for contracts involving ADP services, such as a FA operating an MMIS, the requirements under 45 CFR 95 must be satisfied by the submission of an APD for prior approval by HCFA.

2083.3 Medicaid Procurement and Contracting.--

A. Failure to Conduct True Competitive Procurements.--Appendix G of 45 CFR Part 74 requires that all procurement transactions, regardless of whether by sealed bids or by negotiation, and without regard to dollar value, shall be conducted in a manner that provides maximum open and free competition. Procurement procedures shall not restrict or eliminate competition. The regulation cites several examples of what is considered to be restrictive. They include but are not limited to: (1) placing unreasonable requirements on firms for them to qualify to do business, (2) noncompetitive practices between firms, (3) organizational conflicts of interest, and (4) unnecessary experience and bonding requirements.

It is imperative that States not impose unduly restrictive requirements upon potential bidders. Provide for an open solicitation of all technically competent contractors and avoid establishing irrelevant conditions which restrict the number of technically competent bidders. For example, do not require that competitors for a FA contract be a health insuring organization to the exclusion of all others. All the necessary Medicaid functions of a FA contract can be performed by several types of potential contractors including firms possessing data processing capabilities. Limiting the solicitation of insurance firms which only have an exclusive ability to underwrite risk is not within the spirit of a true competitive procurement.

B. Procurements are Inadequately Publicized.--Appendix G requires that proposals be solicited from an adequate number of qualified sources to permit reasonable competition consistent with the nature and requirements of the procurement. Publicize the RFP and honor reasonable requests by other sources to compete to the maximum extent practicable.

Local notice of the solicitation or merely sending copies of the RFP to several prospective contractors is inadequate compliance with this provision. It is recommended that procurements for substantial Medicaid services or equipment be publicly announced via notice in the Commerce Business Daily as well as by publication in an appropriate regional newspaper.

C. Procurement Documents Are Improperly Utilized.--The nature of a procurement for FA, MMIS or ADP services/equipment suggests that the method of procurement be by competitive negotiation. Prepare a procurement document in order to obtain the best possible service or equipment at the lowest reasonable cost.

Do not include technical or other specifications in the RFP that only a single contractor can meet. Do not modify the RFP after issuance when the change tends to place a single contractor in a preferred position. Prepare the evaluation criteria so as not to favor a particular contractor. Evaluation of proposals must be uniform and not based upon a desire to award the contract to a particular contractor. Avoid awarding the contract based on a proposal which does not meet the published requirements of the RFP. Any deviation from this procedure should be for good cause only and justified in writing.

2083.4 Federal Financial Participation and the Review and Approval Process.-

A. Fiscal Agent Procurements.--If a FA procurement contains or involves the operation of an MMIS or ADP services, it must conform with 45 CFR 95 and 42 CFR 433.

B. Medicaid Management Information Systems Acquisitions.--The FFP regulations for MMIS acquisition (See 42 CFR 433.112) specify that FFP is available at 90 percent in expenditures for design, development, installation or improvement of a mechanized claims processing and information retrieval system if the system is approved by the Administrator. This applies regardless of how the system is operated; i.e., by the State or by a FA. FFP is also available at 75 percent of expenditures for operation of the system as approved by the Administrator. The regulation imposes upon the recipient the procurement and procedural requirements of other pertinent HHS regulations and procedures including those of 45 CFR Part 74 and 45 CFR Part 95, Subpart F.

C. Acquisition of Automatic Data Processing Equipment and Services.--Acquisitions of this type are subject to prior approval conditions for FFP in 45 CFR 95, Subpart F. Where the SA requests FFP funding for equipment and services under multiple titles of the Social Security Act, the ASMB of the Department is the coordinating component for such requests; approval authority rests with the component(s) authorized by the titles involved. Direct requests for title XIX funding only concurrently to the ASMB and the appropriate HCFA RO.

1. Specific Conditions for Federal Financial Participation.--The regulation at 45 CFR 95.611(b) requires prior written approval from HHS or HCFA for the documents indicated:

a. Service Agreement.--Obtain prior approval for the service agreement when data processing services are to be provided by a State central data processing facility or by another State or local agency.

b. Request for Proposals.--Obtain approval for the RFP prior to its issuance when ADP service or equipment proposals are solicited from commercial sources.

c. Contract Document.--Obtain approval, when required, for the contract prior to signature of the contracting officer. HHS requires approval of the contract for complex procurements where the grantee has a history of performance problems or where a procurement is subject to 45 CFR 95.

d. Other Documents.--Finally, obtain prior approval, when required, for the feasibility study, the system study, the system design, the system specifications and the acceptance document.

HHS or HCFA notifies the SA if such prior approval is required in the circumstances discussed in c. and d., above.

2. Notification to the States.--The regulations impose upon HCFA and HHS the responsibility for communicating approval or disapproval of the document within thirty (30) days. If it cannot be done within this period, HHS or HCFA notifies the State regarding the request's status.

3. Prior Notice Requirements.--The regulations specify that proposed acquisitions costing between \$25,000 and \$100,000, while not requiring prior approval, do require the SA to give prior notice. The conditions for prior notice are in 45 CFR 95.612.

2083.5 Suggested Procurement, Review and Contracting Procedures.--The volume and complexity of new contracts have made it virtually impossible for HCFA to approve, in a timely manner, contracts submitted close to the anticipated execution date or after they have been executed. Under current regulations, HCFA cannot prevent States from losing valuable time which could possibly be critical to implementation schedules. To give HCFA the opportunity to conduct

timely review of precontract procurement documents at the earliest stages of the procurement process and to alert a State to possible violations of Federal requirements, certain procedures are recommended. In addition to insuring open and free competition, the recommendations permit early review and approval by HCFA for the basic procurement documents regardless of the nature of procurements as long as the anticipated cost exceeds the monetary threshold in 45 CFR 95.611 or involves enhanced FFP at the 90 percent level. This includes the following: (1) the APD; (2) the RFP; (3) the evaluation plan for the proposals received by the SA; (4) the selection committee report; and (5) the proposed final contract.

A. Outline of Specific Steps By Procurement Document.--The following outline includes suggested steps to take in procurements of FA services (regardless of whether or not MMIS and/or ADP is also involved) and MMIS and ADP equipment and services when the anticipated cost or expenditures are expected to exceed \$100,000. Timeframes are suggested where applicable. The suggested procedures and instructions are referable generally to all procurements involving over \$100,000 or enhanced FFP.

1. Advance Planning Document.--

a. Simultaneously submit a copy of the APD to the ASMB in accordance with 45 CFR 95.611 and to the appropriate HCFA RO (attention ARA,DFO).

b. Submit the APD at least sixty (60) days prior to the anticipated date for issuance of the RFP and at least nine (9) months before the effective date of the new contract.

c. The HCFA RO will solicit CO comments during its review of the documents and notify the SA of its determination.

d. Notice of approval, disapproval or request for additional information regarding the APD will be sent no later than thirty (30) days from receipt of the document. Where additional information is requested, notice of approval or disapproval will be sent to the SA no later than thirty (30) days after receipt of such additional data.

2. Request for Proposal.--

a. Send a copy of the draft RFP to the RO at least forty-five (45) days prior to the proposed issuance date. The proposed final RFP should be received by the ASMB and the RO at least thirty (30) days before the formal issuance date.

b. Review and exchange of written comments by the RO and CO with a recommendation of approval or disapproval will be sent to the SA by the HCFA RO no later than thirty (30) days from receipt of the proposed final document.

c. Advertise the notice of intent to issue an RFP in several publications customarily used for such purposes; e.g., nationally, we suggest the Commerce Business Daily along with at least one other appropriate professional publication in the local area. Additionally, send a notice to organizations known to be generally interested in, and qualified to perform, the work contemplated.

d. Permit potential contractors at least sixty (60) days from the RFP issuance date to submit their proposals. If feasible, allow a greater period, up to ninety (90) days, to encourage more contractors to submit responsive proposals.

e. Include the general evaluation criteria and relative values to be used in evaluating proposals and selecting finalists.

f. Include, where possible, a copy of the State's proposed contract.

3. Proposal Evaluation Plan.--

a. During the same period allowed for RFP preparation, prepare and submit a comprehensive PEP to the RO for review and comment.

b. If unable to be completed by the SA and approved by HCFA prior to RFP issuance, the PEP must be finalized before any proposals are opened. The PEP must not be made available to prospective bidders under any circumstances prior to evaluation and award. Release of any evaluation material after award is discretionary and is subject only to the SAs respective procurement regulations or policies.

c. Using the approved PEP, complete the evaluation for all proposals received within thirty (30) days of their opening.

4. Report of Selection Committee.--

a. Submit to the RO a report of the selection committee, including its summary analysis of proposals received immediately upon completion of the evaluation process.

b. Approval by HCFA should follow within twenty (20) days unless the selection, on its face, either violates Federal procurement regulations or does not follow the pre-established RFP criteria.

c. Delay formal announcement and/or commencement of contract negotiations until HCFA approves the selection report.

5. Contract.--

- a. Conclude negotiations with the successful contractor within sixty (60) days from their commencement.
- b. Include appropriate language to coincide with all pertinent requirements and conditions of the RFP and proposal.
- c. Conform to the general contract requirements of 42 CFR 431, Subpart L previously discussed in §2080 through 2082.3 of this manual, and include all appropriate socio-economic Federal requirements and clauses.
- d. Submit an early draft contract on a timely basis to the RO for preliminary HCFA review and comments.
- e. Submit the proposed final contract to the ASMB in accordance with 45 CFR 95.6ll. Send a copy simultaneously to the HCFA RO (to the attention of the ARA, DFO).
- f. The HCFA approval of the final contract document should be sent within thirty (30) days of its receipt.
- g. Do not execute the contract until the final document receives HCFA approval.

B. Checklist for Procurement Documents.--A yes-no type checklist for each of the several documents comprising the normal procurement process follows. The checklist's purpose is to aid or guide the SA, RO and CO in the preparation and/or review of the respective procurement documents. The checklists are suggestive of the elements to include in the several documents and are not all inclusive.

1. Advance Planning Document Checklist.--

- a. Was a feasibility study conducted to determine whether a procurement process should be initiated? Areas for consideration include cost, time constraints, resource availability, projected savings, and increased efficiency. If cost savings or other factors clearly show the need for the procurement, no feasibility study is required.
- b. Is there a need shown for the specific service or system?
- c. If a health insurance contract is involved, is sufficient rationale included that this method of contracting is a proper and efficient method of program administration?
- d. Is there a plan of action for the major tasks involved in the procurement process such as issuance of a RFP, the advertising plan and basic evaluation procedures?

e. Is the timeframe for each major task adequate to insure that a sufficient number of qualified bidders will participate and that appropriate review time is provided?

f. Is a proposed budget for the procurement included with a breakout of administrative costs and benefit payments?

g. Are the principal features of the proposed contract included?

(1) Type of contract, e.g., FA, health insurer.

(2) Method of compensation, e.g., fixed-price, fixed rate.

(3) Term of contract.

(4) Anticipated cost, including cost to State Medicaid program and anticipated FFP.

h. Are the proposed savings resulting from the planned contract listed; e.g., if a contract for management consulting services is involved, are the expected benefits and associated dollar savings resulting from improved management techniques addressed?

i. Is there an acceptable plan for monitoring the contract and evaluating the selected contractor's performance?

2. Request for Proposals Checklist

a. Are the major timeframes of the RFP for response by competitors, evaluation period, award, contract negotiation, implementation and contract start-up time adequate to assure interested contractors a sufficient period to prepare a proposal and assume operations in an orderly manner?

b. Does the RFP contain a detailed and clear description of the scope of work to be contracted?

c. Does the RFP provide for:

(1) Answering written questions from a prospective bidder about the RFP?

(2) Optional inspection of the State site by an bidder?

(3) Acceptance of a late or alternate proposal or withdrawal of a proposal?

(4) Authorization from a parent, affiliate or subsidiary organization, for the State to have access to its records if such a relationship exists as would impact upon the bidder's performance under the proposed contract?

(5) Evidence of adequate financial stability of the bidder and of any parent organization?

(6) Performance standards?

(7) A timeframe requirement for guarantee of all prices quoted in the proposal?

(8) Acceptance by an bidder of any reduction in payments for nonperformance?

(9) A bidders' conference?

(10) The general overall evaluation criteria, including maximum points available by category?

d. Does the RFP provide for free and open solicitation of technically competent contractors? Do not require that competitors for a FA contract be a health insurance organization.

e. Is the contract term adequate to provide an incentive to qualified bidders? Make large FA contracts for a term of at least three (3) years duration but no longer than five (5) years including all annual optional renewal periods (State law permitting). They must, in all cases, be for a specified period.

f. Does the RFP list procedures for handling changes to the RFP which occur after some proposals are submitted, identify who will be notified of the changes and describe how they will be made?

g. Are there any requirements in the RFP that would unduly restrict or limit true competition among prospective bidders?

h. Is there any conflict in the RFP between State and Federal procurement law or regulations?

i. Does the RFP include a copy of the State's proposed contract?

3. Proposal Evaluation Plan Checklist.--

a. Does the PEP consider the following in the evaluation of proposals?

(1) Contractor Capability

- Staff qualifications and general experience.
- Experience with title XIX or similar programs.
- Availability of necessary equipment.
- Contractor stability (including financial stability and reputation in the field).
- Evaluation by previous clients.
- Willingness to commit specific personnel to the job (by name, position, and/or experience).

(2) Technical Approach

- Understanding of the scope, objectives, and requirements.
- Proper emphasis on various job elements.
- Responsiveness to specifications.
- Clarity of statement of implementation plan.
- Adequacy of work scheduling.
- Adequacy of project control.
- Adequacy of turnover tasks.

(3) Financial Aspects

- Realism of total cost estimate and cost breakdown.
- Realism of estimated hours of staff time.
- Hourly rate structure.
- Reasonableness of implementation costs.
- Reasonableness of turnover costs.

b. Other Considerations.--

(1) Are weights assigned to factors which would give an unfair advantage to particular prospective bidders?

(2) Are any evaluation factors restrictive; e.g., is the bidder instructed to list only experience in one program, such as Medicaid, rather than in others in which the bidder is experienced?

4. Report of the Selection Committee Checklist.--

a. If a contractor which did not submit the lowest offer was selected, was its selection justified as being most advantageous to the State?

b. Is the selection committee's tabulation of proposal scores complete and accurate?

c. Is the evaluation process free of bias?

d. Is a meeting for debriefing of unsuccessful bidders offered after the announcement of the contract award?

e. Did the evaluation committee substantiate reasons a prospective bidder was determined to be nonresponsive?

f. Did the evaluation committee document valid reasons for not awarding the maximum points in each category and/or the reasons for awarding bonus points?

5. Proposed Contract Checklist.--

a. General Provisions. --

(1) Equal Employment Opportunity: Contractor must abide by Federal standards.

(2) Cost and Pricing Data: Contractor must submit cost and/or pricing data as required.

(3) Inspection: State and HHS must retain the right to inspect contractor's facilities.

(4) Use of Information and Data: All information accumulated under contract belongs to the Medicaid program.

(5) Cooperation: Contractor must fully cooperate with necessary audits, program reports, etc.

(6) Disputes provisions: Contractor must abide by disputes procedures outlined in the contract.

b. Special Provisions.--

(1) Books and Records: Specify the exact documents which the contractor must maintain and that the State and HHS must have access to them.

(2) Confidential Nature of Records: The confidentiality of the patient's medical data must be recognized and use of the records limited to program audit functions.

(3) Subcontracts: Any subcontracts must be referenced and attached to the contract.

(4) No Assignment: Do not allow the contractor to assign risk and/or liability to a subcontractor.

(5) Insurance: Specify any provisions for reinsurance of a program.

(6) Third-Party Liability: Specify the extent and term of any third-party liability.

(7) Performance Bond: Provision for a performance bond must be equitable and not restrict competition.

(8) State Employees Not to Benefit: State employees must not benefit from the awarding of the contract.

(9) Warranty Against Broker's Fee: The contract must contain a warranty provision prohibiting the payment of a brokerage fee.

(10) Contractor's Independent Use of Program Data: Do not permit the contractor to use program data for independent projects without prior written permission from the State.

(11) Purchase or Lease of System: Retain a license to purchase or lease the system upon conclusion of the contract.

(12) States may require contractors' assistance in running parallel system for conversion in-house or to subsequent contractor.

(13) The amount of liquidated damages must be reasonable in light of the particular performance required.

c. Definitions--

(1) Eligible Person (Recipient): Clearly define the population groups covered by the contractor.

(2) Eligible Provider: Include an exact definition of eligible providers.

(3) Covered Benefits: Delineate the services and supplies covered by the contract.

(4) Provider Agreement: Define the extent and terms of the provider participation agreement.

(5) Claims: Include a definition of what constitutes a valid claim.

d. Contractor Services--

(1) General Duties and Obligations: Delineate the duties and obligations of the contractor.

(2) Claims Processing Duties: If appropriate, specify the claims processing duties of the contractor.

(3) Claims Auditing and Surveillance of Fraudulent Activities: In addition to specifying how the functions will be carried out, delineate responsibility requirements.

(4) Special Reports: Specify any special reports required.

e. State Responsibilities.--

(1) General Duties and Obligations: Delineate the duties and obligations of the State.

f. Certification and Identification.--

(1) Certification of Eligible Providers: Define the responsibility for and the procedures for provider certification.

(2) Certification of Eligible Persons: Define responsibility for and the procedures for eligibility determination.

(3) Eligible Person Identification: Establish the method for determining recipient eligibility.

g. Amounts Payable to Contractor.--

(1) Advance Payments: Include a provision that payments to the contractor prior to actual performance of services rendered are prohibited.

(2) Funds for Payment of Claims: Specify the procedure for allocating funds for the payment of claims.

(3) Payments for Fiscal Agent Services: Specify the procedure and timing for reimbursing the contractor for FA services.

(4) Availability of Records: Delineate the documentation requirements of the contractor prior to payment.

(5) Provider Reimbursement: Specify the mechanisms for reimbursing providers.

(6) Adjustments: List the procedure(s) and circumstances for an adjustment of contractor charges. Limit them in scope.

h. Program Change Procedures.--

(1) Contractor Proposals: Define the mechanism and criteria for evaluating and acting upon contractor initiated proposed changes.

(2) Required Program Changes: Specify the mechanism for implementing required program changes during the contract.

i. Continuous Contract Performance.--

(1) Specify the method of monitoring contractor performance.

j. Contract Termination and Extension.--

(1) **State Termination of Contract:** Delineate the procedures for termination of the contract, e.g., termination for default and/or convenience, in accordance with the provisions of 45 CFR Part 74 (paragraph 14b, appendix G).

(2) **Extension Periods:** A justification for any contract extension should clearly support its need and duration. Limit it in scope and duration.

(3) **Rights to Obtain and Use System and Computer Programs:** The right of the State to legally obtain and use the system programs and associated materials for subsequent purposes must be definitive.

(4) **State's Right to Data:** Retain the right to maintain and control the use of the data accumulated under the contract.

(5) **State's Limited Liability:** The State's liability under the contract should not exceed the amount of Federal and State funds approved for the contract.

2084. MEDICARE AND MEDICAID HEALTH AND SAFETY STANDARDS

The Social Security Act mandates the establishment of minimum health and safety standards which must be met by providers and suppliers participating in the Medicare and Medicaid programs. The Secretary of Health and Human Services has designated the Health Care Financing Administration (HCFA), and within HCFA the Health Standards and Quality Bureau (HSQB), to administer and/or monitor the standards compliance aspects of these programs. Differences in the programs are significant in determining whether the providers and suppliers may participate in one program or both.

A. Medicare Provisions.--Medicare is a Federal insurance program providing a wide range of benefits for specific periods of time through providers and suppliers participating in the program. Providers, in Medicare terminology, are patient care institutions such as hospitals, hospices, nursing homes and home health agencies. Suppliers are agencies for diagnosis and therapy rather than sustained patient care, such as laboratories, clinics and physical therapist offices. The Act designates those providers and suppliers subject to Federal health care quality standards. Benefits are payable for most people over age 65, Social Security beneficiaries under 65 entitled to disability benefits, and individuals needing renal dialysis or renal transplantation. Payment for services is made by the Federal government through designated fiscal intermediaries to the providers and suppliers.

B. Medicaid Provisions.--Medicaid is a State-administered program to provide payment for medical services to clients of certain public assistance programs and other needy individuals at the State's option. States may decide on an amount, duration and scope of services, except that care in institutions primarily for the care and treatment of mental disease may not be included for persons over age 21 and under age 65. When services are furnished through the types of institutions approved for Medicare, the Medicare institutional standards must be met for Medicaid as well. Intermediate Care Facilities including Intermediate Care Facilities for the Mentally Retarded, are required to meet Federal Medicaid standards. Medicaid Skilled Nursing Facilities must meet Medicare standards even if they do not participate in Medicare.

2084.1 The Basis for State Certification Agency Activities Under Title XIX of the Social Security Act.--Section 1864(a) of the Act directs the Secretary to use the State health agencies (SAs) or "other appropriate agencies" to determine whether health care institutions meet standards. This helping function is termed provider certification.

Section 1902(a)(9)(A) requires that a State use the same agency to establish and maintain additional standards for the State Medicaid program. Section 1902(a)(33)(B) requires that the State agency licensing health institutions (in effect, the same agency) also determine whether institutions meet all applicable Federal health standards for Medicaid participation, subject to validation by the Secretary of Health and Human Services.

Federal requirements are published in the Code of Federal Regulations, Title 42, Chapter IV.

2084.2 Health Care Financing Administration's Medicaid Monitoring Role.--Overall policy-making responsibility is centralized in HCFA's headquarters, where all aspects of the Medicare program and oversight of the State Medicaid programs are coordinated. The Health Standards and Quality Bureau, located in Baltimore, is responsible for:

- o Monitoring, surveillance, and overall administrative control of the certification process including its financial aspects,
- o Establishing operational policy for the certification process, and
- o Conveying operational instructions and official interpretations of certification policy to the SAs, State Medicaid agencies, and the HCFA regional offices (ROs).

Within each of the ten HCFA ROs, the Division of Health Standards and Quality (DHSQ) is responsible for assuring that health care facilities participating in the Medicaid program meet applicable Federal requirements. This is accomplished through various activities. The RO:

- o Evaluates the performance of SAs in applying and enforcing health and safety standards, the States' assessments of facilities for compliance with standards, and the States' adherence to required and appropriate administrative procedures.
- o Provides liaison, direction and technical assistance to SAs in the day-to-day management of the certification process.
- o Explains the meaning and applicability of HCFA guidelines, policies and procedures applicable to certification activities.
- o Analyzes certification budgets and State spending patterns to assure that funds are economically and appropriately utilized; allocates SA funds for conducting certification activities.

- o Monitors and assesses SA operations and assists them in developing the capability to provide direct assistance to providers and suppliers; reviews all certification actions and provides feedback to States.
- o Prepares data based on SA survey findings for input into HCFA's Medicare/Medicaid Automated Certification System (MMACS); analyzes MMACS data and provides feedback to the SAs on certification information tracked by the system.
- o Conducts Federal surveys of facilities to ensure that standards and procedures are applied in a uniform and consistent manner.
- o Monitors Medicaid long term care services to preclude Federal Financial Participation in State payments to facilities without valid provider agreements.

2084.3 Determination-Making Authority.

A. Medicaid Approval.--Medicaid law requires that the same State agency/(SA) that certifies Medicare provider and supplier eligibility also make the determinations of eligibility to participate in Medicaid. The law also requires that there be a separately designated single State agency responsible for the overall management of the Medicaid program. Therefore, in each State, a State Medicaid agency is ultimately responsible for Medicaid program administration. Each State Medicaid agency enters into an interagency agreement with the certifying SA establishing the determination-making function of the certifying SA and providing for the application of Federal certification standards and procedures. The State Medicaid agency must accept the other SA's certification decisions as final, but exercises its own determination whether to enter into agreements with approved skilled nursing facilities (SNFs) and intermediate care facilities (ICFs), including intermediate care facilities for the mentally retarded (ICFs/MR). The State Medicaid agency is responsible for reviewing certifications to ensure that the SA has adhered to procedural requirements. If the State Medicaid agency disagrees with the SA's certification, it first contacts the SA to resolve the issue. If the issue cannot be resolved, the State Medicaid agency contacts the HCFA RO.

B. Waivers of Standards.--For a few of the standards, the statute or regulations allow for waivers in the presence of verified temporary shortages of health personnel or in the presence of equivalent alternative patient safeguards. Waiver authority is redelegated to the HCFA ROs, except for waivers on ICFs which repose with the States.

C. Look-Behind Authority.--HCFA has the authority to "look behind" State determinations and, with cause, to make binding determinations (section 1902(a)(33)(B)). HCFA has two kinds of look behind authority. It has

authority to cancel the approval of a SNF or ICF to participate in the Medicaid program when HCFA determines that the facility fails to comply substantially with the Conditions of Participation, 42 CFR 405, Subpart K (SNFs) or with the standards contained in 42 CFR 442, Subparts D, E, F, or G (ICFs). In these instances the cancellation is usually effective after the provider has had the opportunity for a formal hearing. If, however, an immediate and serious threat to patients' health and safety is determined, the hearing before a Federal Administrative Law Judge will be afforded after the effective date of cancellation. Federal financial participation (FFP) payments cease on the effective date, except that additional FFP may be available pursuant to 42 CFR 441.11.

The other look behind authority provides that a provider agreement is considered by HCFA to be invalid for purposes of providing FFP to the State if the State failed to adhere to Federal procedures. For example, the State Medicaid agency may have issued the provider agreement even though the SA certified the facility as not being in compliance. In that case, the agreement is void from its inception. The State would not be entitled to FFP in any bills related to that facility. This authority is established by 42 CFR 442.30.

D. Authorization of Certification Expenditures.--Authority to approve Medicare certification budgets and expenditures is delegated to the HCFA Regional Administrators. Authority to approve or disapprove FFP in Medicaid certification expenses is also delegated to the Regional Administrators.

E. Appeals.--If a Medicaid-only facility requests a hearing, such hearing must be completed either before, or within 120 days after, the effective date of the adverse action. (See §2040.) Detailed Medicaid appeal procedures are provided by the State. When a facility participates in both the Medicare and Medicaid programs, any Medicare adverse action also applies to Medicaid, including the Medicare appeal procedures. In the case of "look-behind" terminations, HCFA notifies the facility of the termination and whether it has a right to request a hearing before a Federal Administrative Law Judge. A facility has no right to an appeal in cases where HCFA disallows FFP on the grounds that the State certification agency has improperly certified the facility.

2084.4 Functions of the State Certification Agency.--Certification functions of the SA include:

A. Identifying Potential Participants.--Medicaid patients are guaranteed that at least hospital, SNF and other (optional) services are available on a Statewide basis.

B. Conducting Investigations and Fact-Finding Surveys.--The SA conducts onsite inspections of facilities to ensure compliance with Conditions of Participation and standards.

C. Certifying and Recertifying.--Section 1902(a)(33)(B) requires that the SA determine whether institutions and agencies meet the requirements for participation. Certifications are periodically forwarded to the appropriate Federal Medicare or State Medicaid agencies regarding whether or not institutions are qualified to participate in the programs.

2084.5 Explanation of Certification and Survey.--SAs survey and certify whether facilities meet the requirements for participation in the Medicaid program. The SA's finding constitutes a determination. You can only enter into a valid provider agreement when the SA finds the facility to be in compliance.

Onsite surveys are usually necessary for the SA to be able to certify. The law provides Federal funding for these surveys. SAs survey many institutions simultaneously for Medicare, Medicaid and State licensure, and sometimes for other inspection programs, so the costs must be allocated between the programs on an equitable apportionment basis.

Part of a survey may concern a provider's effort to prevent environmental hazards due to contagion, fire, contamination, or structural design and maintenance problems. However, a survey is not a mere building inspection nor a "white glove inspection" which, on no more than an annual basis, would be pointless. Its more realistic focus is on ascertaining that the responsible facility officials and key personnel are effectively doing all they must do to protect health and safety. Thus, many aspects of the survey are accomplished by scrutinizing the facility's records to ascertain whether professional staff members have been properly noting and evaluating the progress of patients' care or managing facility operations with continuing vigilance. If an established facility complies in these ways, the certification will not be questioned merely on grounds that the facility has expanded or moved or slightly modified the scope of its services--unless it might thereby have changed its character or type of certification.

2084.6. Relationship of Survey Date to Date of Initial Medicaid Approval.--A long term care facility cannot have its services covered and reimbursed by Medicaid until the date on which it is found, via the certification process, to be in compliance with all applicable Conditions of Participation if it is a SNF or standards if it is an ICF. Since it usually is impossible to schedule and complete a survey, i.e., to ascertain actual compliance with all applicable requirements, on the date a new facility opens its doors, a new facility generally must operate for a short initial period without Medicaid reimbursement for its services.

2084.7 Approval to Participate and Correction of Deficiency Citations.--The Conditions of Participation and standards are requirements for acceptable quality in the operation of health care facilities. There is a set of requirements for each type of facility subject to SA certification. Subsidiary to each Condition is a group of related quality standards, with the Condition expressed in a summary lead sentence or paragraph characterizing the quality or result of operations to which all the subsidiary standards are directed. While a facility may fail to comply with one or more of the subsidiary standards during any given survey, it cannot participate in Medicaid unless it meets each and every applicable Condition. (Many Condition summaries are identical to statements of requirements set forth in section 1861 or other parts of the statute.) The essence of what the SA certifies to Medicaid is a finding whether each facility meets each of the Conditions (or for ICFs, standards) applicable to it.

When the SA cites a facility for its failure to meet an eligibility requirement, the citation is referred to as a "deficiency." A deficiency does not necessarily mean that the facility is negligent, or furnishing care of a poor quality. A deficiency may indicate that circumstances or inferior administrative practices create the potential for accidents, negligence, or poor care. A facility may be "deficient" in meeting program requirements without posing any threat to patients.

The SA will give the facility a Statement of Deficiencies if any deficiencies are cited. The facility is given a short time in which to respond with a Plan of Correction for each cited deficiency. It enters the response on the form containing the Statement of Deficiencies. (This form is then disseminated for public inspection at the nearest HCFA and State welfare offices.)

If the facility is not in compliance with all Conditions, the SA must certify noncompliance notwithstanding a Plan of Correction. The adjudicative process is begun which may culminate in termination of the institution's participation.

Following a certification of noncompliance, the State Medicaid agency either suspends payments for new admissions or takes action to terminate a noncomplying facility's Medicaid agreement.

2085. SPECIFIC REQUIREMENTS FOR HEALTH MAINTENANCE ORGANIZATIONS (HMOs) AND CERTAIN HEALTH INSURING ORGANIZATIONS (HIOs)

The following are definitions of terms related to managed care:

A. Actuarially Sound Payment.--HMO contracts must describe actuarial (projection of utilization and costs for specific benefits for a defined population) basis and methodology used to compute capitation rates. Fees and any other payments provided for in the contract cannot exceed the fee-for-service upper payment limit. (See §2089.3.) Actuarially sound payment is discussed in §2089.2.

B. Capitation.--This is the per capita cost of providing a specific menu of health services to a defined population for a prescribed period of time (usually one month). This is paid by the agency to a contractor for the provision of medical services under the State Plan, whether the recipient actually receives the services during the period covered by the fee.

C. Contractor.--A contractor is an entity that contracts with you under a State Plan and, in return for a payment, processes claims, pays for or provides medical services or enhances your capability for effective administration of the program. A contractor may be a fiscal agent, a health care project grant center, a private nonmedical institution, an HMO, a prepaid health plan, a clinical laboratory or a professional management service or consultant firm.

D. Federally Qualified HMO.--A Federally qualified HMO has fulfilled the requirements of the HMO Act, its amendments and the regulations.

E. Fee-for-service Upper Payment Limit (FES-UPL).--This is the upper limit of what it would have cost to provide the same services under regular fee-for-service Medicaid to an actuarially equivalent population. (See §2089.3.)

F. Grievance Procedure.--This is the process by which an enrollee expresses dissatisfaction with the HMO and seeks recourse. (See §2091.7.)

G. Health Insuring Organization (HIO).--This is an entity that: (1) pays for medical services provided to recipients in exchange for a premium or subscription charge paid by you and (2) assumes an underwriting risk.

H. Health Maintenance Organization (HMO).--This is a public or private entity organized under State law that is either Federally qualified or meets the State Plan's definition of an HMO.

I. Insolvency.--An insolvent organization is unable to pay debts when due, even though assets may exceed liabilities. (See §2086.6.)

J. Prepaid Health Plan (PHP).--This is an entity that provides medical services to enrolled recipients (under contract with you on a prepaid capitation basis) but does not qualify as an HMO.

K. Recipient.--A recipient is an individual entitled to Medicaid benefits and may also be referred to as enrollee.

L. Reinsurance.--This is insurance purchased by an HMO from insurance companies to protect against part of the costs of providing services to its members.

M. Risk--Risk based contracts are those in which the organization is at risk of incurring loss if its cost of providing services is more than the capitation payments. (See §2085.2.)

N. State Plan Defined HMO--If an HMO is not Federally qualified, it must meet the HMO definition specified in the State Plan and meet the requirements of 42 CFR 434.20(c). (See §2086.5.)

O. Stop-Loss--This is a provision in an HMO contract used to limit the HMO's financial liability for any enrollee whose costs exceed a certain level in a certain period. (See §2089.6.)

P. Third Party Payment--This is payment for health care, in part or whole, by an insurance company or other organization so that the patient does not directly pay for the services. (See §2089.7.)

The Federal health maintenance organization (HMO) requirements are primarily based on §1903(m) of the Act and 42 CFR 434. This section describes the requirements that generally apply to contracts for comprehensive services (see §2085.1) under which payment is made on a capitation or other risk basis. (See §2085.2.) Unless one of the exceptions set forth below applies, you must meet these requirements in order to receive Federal Financial Participation (FFP) in payments under such contracts. You may impose additional requirements as long as they do not conflict with the Federal requirements.

A capitation contract includes periodic payments which are based on prospectively determined rates per member per month and the number of Medicaid recipients enrolled in the organization for that period. Other risk based contracts include any contract under which the HMO is at risk, as defined in §2085.2.

The first requirement that must be met by an entity seeking to contract to provide comprehensive services on a risk basis is that the entity meet the Medicaid definition of an HMO. (See §2086.) This definition does not necessarily correspond to definitions employed in other Federal programs (e.g., title XIII of the Public Health Service Act and title XVIII of the Act) or in the managed care industry.

2085.1 Comprehensive Services--An organization offers comprehensive services if it contracts to provide or arrange for, at a minimum, the combination of services described in subsections A or B:

- A. Inpatient hospital services and one or more services or groups of services as follows:
 - o Outpatient hospital services and rural health clinic services;
 - o Laboratory and X-ray services;
 - o Nursing facility (NF) services for persons aged 21 and older, early and periodic screening and diagnosis of persons under age 21, and family planning services and supplies to persons of childbearing age;
 - o Physician services; and
 - o Home health care services.

B. No inpatient services, but three or more services or groups of services listed in subsection A.

Where one or more services on the list is grouped together on the same line, the organization may offer any or all of the services in the group. When one or more services from a group is selected, the group is counted once toward meeting the comprehensive service definition of three or more services.

For example, an organization provides comprehensive services if it contracts to provide inpatient hospital services and physician services. An organization also provides comprehensive services if it contracts to provide physician services, lab and X-ray services, and family planning services and supplies. An organization does not provide comprehensive services if it contracts to provide physician services and lab and X-ray services, because lab and X-ray services are treated as a single group of services.

An organization may contract to offer any number of other medical services which are not on the list. These services have no effect on meeting the definition of comprehensive services. (See §§1903(m)(2)(A) and 1903(a)(9) of the Act and 42 CFR 434.21.)

Capitated entities do not need to meet the requirements of §1903(m) of the Act if services are less than fully comprehensive. Under a partially capitated system, you may contract with a physician, physician group, or clinic for a limited range of services under capitation. Any combination of less than three of the services listed in subsection A is defined as a prepaid health plan (PHP) and not subject to this section of the manual.

Or, if inpatient hospital services are capitated but none of the services listed in subsection A are capitated, the entity is considered a PHP. In certain instances, when services are furnished in a clinic setting, all the services furnished (i.e., physician, laboratory, x-ray, etc.) may be considered clinic services.

2085.2 Payment on Risk Basis.--Under a risk basis contract, the insuring organization is at risk of incurring a loss if its cost of providing services exceeds its payments. It may retain a profit if its cost of providing services is less than its payments. Under a risk contract, the payments are the total payments to the organization. There is no retroactive payment adjustment to reflect the cost of services actually provided. (See 42 CFR 434.21.)

2085.3 Section 1115 Demonstration Projects.--You have the option of requesting exemption from certain Medicaid HMO requirements in order to operate a §1115 managed care demonstration. Compliance with §1902 of the Act can be waived and State payments which, under §1903 of the Act, are not normally eligible for FFP, can be Federally matched. The demonstrations are approved for the purpose of evaluating specific managed care interventions and thus must be designed so that specific research issues can be investigated. Arizona's Medicaid program is one such organization which has requested and received exemption from specific HMO requirements in its statewide managed care demonstration program.

2086. ELIGIBILITY FOR FFP

The requirements that generally apply in determining whether an organization is eligible to enter into comprehensive risk contracts in which FFP is provided are based on §1903(m)(1) of the Act and 42 CFR 434.20. An organization is eligible to enter into such a contract once the organization meets the Medicaid definition of an HMO. (See §2086.1.) Unless one of the exceptions set forth in this section applies, no Federal matching funds are available to you for services provided by an entity which has not met the HMO definition and other

requirements. You must also exclude from participation any provider, individual, organization or entity that could be excluded under the regulations from participating in Medicare or Medicaid. (See §2086.16.)

2086.1 Definition of HMO.--An organization must be a public or private entity which is organized under State law. The organization must either be Federally qualified (see §2086.3), or meet the State Plan definition of an HMO. (See §2086.5.)

2086.2 HMO Under State Law.--States have the authority to regulate HMOs and determine what State laws apply to HMOs. Depending upon the State which signs the Medicaid contract, HMOs may be regulated by a variety of State laws including laws governing indemnity insurers, corporations, providers of health care, HMOs or any other laws stipulated by the State.

A health insuring organization (HIO) is an entity that pays for medical services provided to recipients in exchange for a premium or subscription charge paid by you and which assumes an underwriting risk. HIOs that become operational after January 1, 1986 and that arrange for the provision of services must also meet the definition of an HMO in §1903(m)(1) of the Act. Congress has enacted language expressly providing that §1903(m)(1) of the Act may not be construed as requiring that an HIO must be organized under the State HMO laws. The HIO may be organized, for example, under the corporation laws of the State where it does business. The HIO must still meet all other applicable State laws.

2086.3 Determining That Organization Meets HMO Definition.--To be Federally qualified by HCFA, the HMO must meet the requirements of §1310(d) of the Public Health Service Act.

A competitive medical plan (CMP) is an organization which contracts with HCFA to enroll Medicare beneficiaries. Present Medicaid law does not deem that a CMP meet the HMO definition. A CMP must be treated like any other non-Federally qualified entity for purposes of satisfying the requirement that it be an HMO as defined in §1903(m)(1) of the Act. As set forth in §§2090.9 and 2090.13, however, a CMP with a current Medicare contract is entitled to some benefits in the Medicaid program. An organization which is not Federally qualified must be found by the RO to satisfy the requirements applicable to State Plan defined HMOs. (See §2086.5.)

2086.4 Effective Date of Determination.--The effective date is the date on which an organization is determined to meet the HMO definition. For Federally qualified HMOs, the effective date is the date on which the organization becomes Federally qualified. For State Plan defined HMOs, the effective date is the date on which the RO makes a determination that the organization qualifies as an HMO.

You may ask the RO to defer making such a determination until an organization is ready to enroll Medicaid recipients. This assures that the HMO's insolvency provisions, as approved under the State Plan, are current. Also, it gives you a full three year period if you have requested a waiver of enrollment composition since the effective date begins the three year period for which you may request waiver. Waiver of the Federal requirement on the composition of an HMO's enrollment is a State option. (See §§2086.9 through 2086.14.)

2086.5 State Plan Defined HMO.--If an HMO is not Federally qualified and is not exempt from §1903(m)(2)(A)(i), it must meet the HMO definition specified in your State Plan.

2086.6 Adequacy of Insolvency Provisions.--For an organization that is a State Plan defined HMO, the responsibility for protection against the risk of insolvency varies depending upon the State in question and must be determined individually in each State. (See 42 CFR 434.20(c)(3) and 434.50(a).) Adequate protection ensures the subsequent protection of the enrollees if the HMO becomes insolvent (see §1903(m)(1)(A)(ii) of the Act) and ceases operations. Enrollees need protection in two areas. First, they must not be responsible for paying for services received before insolvency. Second, they must continue to receive services through the end of the period for which you have paid the HMO.

As part of the prior approval of the Medicaid HMO contract, the RO has authority to determine whether it is satisfied with the insolvency protection for a State Plan defined HMO. For the Federally qualified HMO, it must meet the Federal qualification requirements for protection against insolvency.

A. Protection for Pre-Insolvency Period.--Before insolvency occurs, the HMO must be able to cover the expense of all services which you have contracted with it to provide, either directly or through subcontractors.

In all cases, the HMO must be able to pay claims for emergency care and for authorized specialty care furnished by out-of-plan providers.

The HMO can often prevent the enrollee from being billed by the HMO's own providers by including "hold-harmless" language in its provider contracts. This language states that the provider looks only to the HMO, and under no circumstances to the enrollee, for full payment of claims. The contract must stipulate that the "hold harmless" clause survives the termination of the contract, including breach of contract due to insolvency.

B. Protection for Post-Insolvency Period.--Insolvency provisions also cover the continued provision of services to HMO enrollees until the end of the month in which insolvency has occurred, as well as the continued provision of inpatient services until the date of discharge for an enrollee who is institutionalized when insolvency occurs. If an HMO ceases operation mid-month, it has already received the Medicaid capitation payment covering services for the entire month. Thus, the HMO is responsible for caring for all of its enrollees through the end of the period for which it has been paid and for its enrollees institutionalized through discharge.

The HMO can require its providers to continue to provide services through the post-insolvency period by including "continuation of benefits" language in its provider contracts. This language states that the providers must continue to provide services to the HMO enrollees through the end of the month in which the HMO becomes insolvent. The providers look only to the HMO, and under no circumstances to the enrollee, for full payment of claims. At the end of the month for which a capitation payment has been made, all enrollees, including institutionalized enrollees, must enroll in any other HMO contracting with you or revert to fee-for-service (FFS). However, where the insolvent HMO pays for institution costs on a cost or per diem basis and you (or another HMO the enrollee has joined) pay institutions a flat fee upon admission, the insolvent HMO is obligated to cover costs through the end of a institutionalization of an enrollee admitted prior to insolvency. Where the insolvent HMO pays institutions based upon a flat fee upon admission, and you (or another HMO the enrollee has joined) pay institutions on a cost or per diem basis, you (or the new HMO) must not make payments for the admission, even if it extends beyond the month of insolvency.

C. Types of Insolvency Provisions.--You must ensure that the HMO has taken steps to insure that in the event of the HMO's insolvency, Medicaid recipients are in no case held liable for services the HMO is legally obligated to cover.

Insolvency protection can take several forms. It can include restricted reserves placed in an escrow account, with the State insurance commission, or any place where the HMO does not have access to the funds until insolvency arises. Insolvency protection can also be obtained by insolvency insurance riders on reinsurance policies, by letters of credit, or by acceptable guarantees from a third party. Insolvency protection is not provided by a reinsurance policy or by stop-loss insurance since reinsurance and stop-loss are no longer an issue once an HMO has entered insolvency and ceased operation.

In addition, the Federal qualification standards require the HMO to set aside money equal to two months' worth of expected expenditures. If the HMO includes "hold harmless" and "continuation of benefits" language in its provider contracts, then it must set aside money to cover two months' worth of expenditures only for out-of-plan providers. To the degree that the HMO is unable to include this language in its own provider contracts, it must also set aside money to cover claims from its own providers for the month before and/or the month after insolvency occurs.

2086.7 Exemption From HMO Definition for Health Centers With Federal Funding in Current and Past Two Years.--Health centers which have received certain Federal funding in the current year and in the past two years do not have to meet the HMO definition. (See §1903(m)(2)(G) of the Act.) They are also exempt from having to meet the enrollment composition requirement (see §§2086.8 and 2086.13) and they may restrict voluntary disenrollment. (See §2090.11.)

To qualify for the exemption from meeting the HMO definition, the health center must be either:

- o A Community or Migrant Health Center which is receiving (and has received during the previous two years) a grant of at least \$100,000 under §330(d)(1) or §329(d)(1)(A) of the Public Health Service Act; or
- o An Appalachian Regional Center which is receiving (and has received during the previous two years) a grant, subgrant, or subcontract of at least \$100,000 under the Appalachian Regional Development Act of 1965.

The RO verifies with the regional Public Health Service staff that an organization is currently receiving (and has received for the previous two years) at least \$100,000 per year in grants funded under the Public Health Service Act. The RO also verifies that the organization receiving the Public Health Service funding is the same legal entity as the one to be exempted from meeting the HMO definition.

Since the Appalachian Regional Development Act funding flows through a block grant to the States in Appalachia, provide the RO with verification of Appalachian funding criterion.

A Federally funded health center which is newly operational and has not received Federal funding for the previous two years does not meet the exemption criterion. It needs to meet the HMO definition and may request a three year waiver of its enrollment composition. Once the new center has been in operation and receiving the appropriate funding for two years, it is entitled to the exemption.

If a Federally funded health center were initially able to satisfy the \$100,000 annual funding criterion for exemption but subsequently lost its Federal funding, it then requests HCFA to determine it meets the HMO definition. In that case, a three year waiver of the enrollment composition could be requested. The approved waiver starts with the date that the RO determines that the HMO definition was met.

2086.8 Requirement of 25 Percent Non-Medicare/Medicaid Enrollment.--Persons eligible for Federal benefits under Medicare and/or Medicaid (referred to as Federal eligibles in this section) must constitute less than 75 percent of the HMO's total prepaid membership. This ratio of 75/25 is the composition of enrollment requirement. (See §1903(m)(2)(A)(ii) of the Act and 42 CFR 434.26(a).)

A person is counted as a single Federal eligible enrollee if he/she is enrolled in the HMO as a Medicare member, a Medicaid member, or a member who is dually eligible for both Medicare and Medicaid.

The 75/25 composition of enrollment requirement applies only to the HMO and not to its subcontractors. The composition of enrollment must be calculated separately for each noncontiguous area within the HMO's catchment area.

2086.9 Enrollment Composition Requirement May Be Waived by RO.--If an HMO cannot meet the composition of enrollment requirement, you may apply to the RO for a waiver of enrollment composition for the HMO. The Associate Regional Administrator for Medicaid may grant an annual waiver under certain circumstances. The annual waiver may be given for no more than a total of three years if the HMO is privately owned, or may be renewed indefinitely if it is publicly owned.

In some situations, an HMO's contract period and waiver period may not be synchronized. At the time of contract renewal, the RO may consider approving the HMO's contract for a full period, contingent on the waiver being successfully extended or the enrollment composition requirement being met.

2086.10 Waiver of Enrollment Composition Requirement for First Three Years.--The RO may waive the enrollment composition requirement for up to the first three years from the date that the HMO is determined by the RO to meet the definition of an HMO. (See §1903(m)(2)(C) of the Act and §2086.4.) The waiver cannot be extended beyond three years if the HMO is privately owned. Once the waiver expires, if 75 percent or more of the HMO's enrollment consists of persons eligible for Medicare and/or Medicaid, FFP is no longer provided for your capitation payments to the HMO.

To apply for a waiver, you must submit the HMO's projected enrollment plan for each year in the three year period to the RO. The RO approves or disapproves the first year of the waiver based on the plan submitted. An acceptable plan must:

- o Provide a general description, including demographic data, of how the HMO plans to enroll at least 25 percent non-Federal eligibles by the end of three years;
- o Include a marketing timetable for achieving the 25 percent non-Federal enrollment;
- o Provide for marketing to non-Federal enrollees, either directly or through a broker;

- o Indicate the groups, including employer groups, to which the HMO plans to market membership;
- o Define the open enrollment period, which may be year round, for non-Federal eligibles;
- o Provide evidence of sound marketing practices. This includes providing commercial enrollees with full and fair information on benefits, coverage, grievance procedures, site locations, hours of service, and numbers and types of participating providers. Marketing literature must be tailored to the education and language of the targeted commercial enrollees;
- o Provide evidence that commercial individuals are given the opportunity to raise questions and discuss their potential membership privately and confidentially with the HMO's representatives; and
- o Provide assurances that quality of care is maintained throughout the three year waiver period.

Each year, on the anniversary date of the three year waiver period, you must provide the RO with a report on the composition of the HMO's enrollment. The report must show, for each of the past 12 months, the number of enrollees who are Federal eligibles and the number of enrollees who are not Federal eligibles. The sum of the two groups must equal the HMO's total prepaid enrollment.

The report must demonstrate to the RO's satisfaction that the HMO is making continuous efforts and progress toward achieving compliance with the enrollment composition requirement. (See 42 CFR 434.26(b)(1) and 434.70.) If you do not submit an annual report, or if the RO is not satisfied with the HMO's progress at the end of the first or second year, the RO may end the waiver. As an alternative, the RO may continue the waiver only on the condition that Federal eligibles be capped at a certain level until a certain composition is achieved, or that no more Federal eligibles be enrolled.

Disapproval or conditional approval at the end of the first or second year is preferable to the RO waiting until even more Medicaid recipients are enrolled at the end of the third year, and then withholding FFP when the HMO cannot satisfy the enrollment composition requirement. At the end of the three year period, the waiver must be terminated and no FFP may be provided if capitation payments are continued to an HMO which does not meet the composition of enrollment requirement.

2086.11 Indefinite Waiver of Enrollment Composition Requirement for Public HMO.--The RO may modify or waive the enrollment composition requirement for HMOs which are public entities, i.e., which are owned or operated by a State, county, municipal health department or municipal hospital. The RO must determine that the HMO has made and continues to make reasonable efforts to enroll persons other than Federal eligibles. (See §1903(m)(2)(D) of the Act and 42 CFR 434.26.)

You must request the waiver on behalf of the HMO and submit the HMO's plan (see §2086.12) for enrolling non-Federal eligibles. You must subsequently provide the RO with annual reports on the actual composition of enrollment in the HMO and the steps that the HMO has taken to increase commercial enrollment.

If the RO is satisfied that the HMO has made and is making reasonable efforts to enroll non-Federal individuals (e.g., enrolling public employees or employees of small businesses), it may approve the waiver for the next year. This waiver must be reapproved each year, but it can be renewed for an indefinite number of years.

2086.12 Waiver of Enrollment Composition Requirement for Certain HMOs.--Federal law allows HCFA to modify or waive the enrollment composition requirement for an HMO which:

- o Is a nonprofit organization with at least 25,000 members;
- o Is (and has been) Federally qualified for a period of at least four years;
- o Provides basic health services through members of its staff;
- o Is located in an area designated as medically underserved under §1302(7) of the Public Health Service Act; and
- o Previously received a waiver of the enrollment composition requirement under authority of §1115 of the Act. (See §1903(m)(2)(E) of the Act.)

For such a waiver to be granted, the RO must determine that special circumstances warrant the modification or waiver and that the HMO has taken (and is taking) reasonable efforts to enroll commercial members. The same documentation in the form of the initial plan and annual reports (see §2086.10) must be submitted for this waiver. The waiver may be reapproved for an indefinite number of years.

2086.13 Exemption from Enrollment Composition Requirement for Health Centers With Federal Funding in Current and Past Two Years.--The statute exempts from the enrollment composition requirement certain Federally funded health centers which have received Federal funding in the current year and past two years. (See §1903(m)(2)(G) of the Act.) To qualify for the exemption from the enrollment composition requirement, the health center must be a:

- o Community or Migrant Health Center which is receiving (and has received during the previous two years) a grant of at least \$100,000 under §§330(d)(1) or 329(d)(1)(A) of the Public Health Service Act; or
- o Appalachian Regional Center which is receiving (and has received during the previous two years) a grant, subgrant, or subcontract of at least \$100,000 under the Appalachian Regional Development Act of 1965.

The RO verifies with the regional Public Health Service staff that an organization is currently receiving (and has received for the previous two years) at least \$100,000 per year in grants funded under the Public Health Service Act. The RO also verifies that the organization receiving the Public Health Service funding is the same legal entity as the one to be exempted from meeting the HMO definition.

Since the Appalachian Regional Development Act funding flows through a block grant to the States in Appalachia, provide the RO with verification of Appalachian funding criterion.

2086.14 Exemption from Enrollment Composition Requirement for Certain HIOs.--A legislative amendment exempted from the enrollment composition requirement any HIO which arranged for provider services if the HIO became operational after January 1, 1986 but is operating under a §1915(b) waiver granted prior to January 1, 1986. This exemption applies during the period that the §1915(b) waiver is effective.

2086.15 Eligibility of New Jersey Medicaid to Operate Garden State Health Plan HMO.--In 1987, Congress enacted a legislative amendment to allow the provision of FFP to New Jersey Medicaid for the operation of the Garden State Health Plan (an HMO owned and operated by the State Medicaid Agency). New Jersey must document in its State Plan and submit to HCFA annually how it satisfies the same Federal HMO requirements which other States must meet in their HMO contracts. The specific requirements for the Garden State Health Plan are not enumerated here but can be found in §1903(m)(6) of the Act.

2086.16 Ineligible Organizations.--Section 1902(p)(2) of the Act stipulates that, in order to receive FFP in your contracts with HMOs, you must exclude from participation all organizations which could be included in any of the following categories.

A. Entities Which Could Be Excluded Under §1128(b)(8) of the Act.--These are entities in which a person who is an officer, director, agent or managing employee of the entity, or a person who has direct or indirect ownership or control interest of 5% or more in the entity has:

1. Been Convicted of the Following Crimes.--

a. Program related crimes, i.e., any criminal offense related to the delivery of an item or service under Medicare or Medicaid (see §1128(a)(1) of the Act);

b. Patient abuse, i.e., criminal offense relating to abuse or neglect of patients in connection with the delivery of health care (see §1128(a)(2) of the Act);

c. Fraud, i.e., a State or Federal crime involving fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of health care or involving an act or omission in a program operated by or financed in whole or part by Federal, State or local government (see §1128(b)(1) of the Act);

d. Obstruction of an investigation, i.e., conviction under State or Federal law of interference or obstruction of any investigation into any criminal offense described in subsections a, b, or c (see §1128(b)(2) of the Act); or

e. Offenses relating to controlled substances, i.e., conviction of a State or Federal crime relating to the manufacture, distribution, prescription or dispensing of a controlled substance. (See §1128(b)(3) of the Act.)

2. Been Excluded from Participation in Medicare or a State Health Care Program.--A State health care program means a Medicaid program or any State program receiving funds under title V or title XX of the Act. (See §1128(b)(8)(B)(iii) of the Act.) The DHHS Office of the Inspector General (OIG) compiles monthly lists of all providers (both individuals and organizations) who have recently been excluded from participation in Medicare

or a State health care program. Twice a year it also generates a list of all providers who are currently included. (After a period of time, providers may be reinstated under certain conditions.) These listings are sent to all State Agencies on a monthly basis as HCFA Publication No. 69, The Medicare/Medicaid Sanction Reinstatement Report. Use these reports to assist you in excluding these providers from contracting with you.

3. Been Assessed a Civil Monetary Penalty Under §1128A of the Act.-Civil monetary penalties can be imposed on individual providers, as well as on provider organizations, agencies, or other entities by the DHHS OIG. Section 1128A authorizes their use in cases of false or fraudulent submittal of claims for payment, and certain other violations of payment practice standards. (See §1128(b)(8)(B)(ii) of the Act.) The OIG does not routinely disseminate lists of entities/individuals which have been assessed a civil monetary penalty, as it does for those excluded from participation in Medicare or Medicaid.

B. Entities Which Have a Direct or Indirect Substantial Contractual Relationship with an Individual or Entity Listed in Subsection A.--A substantial contractual relationship is defined as any contractual relationship which provides for one or more of the following services:

- o The administration, management, or provision of medical services;
- o The establishment of policies pertaining to the administration, management, or provision of medical services; or
- o The provision of operational support for the administration, management, or provision of medical services.

C. Entities Which Employ, Contract With, or Contract Through Any Individual or Entity That is Excluded From Participation in Medicaid under §§1128 or 1128A, for the Provision (Directly or Indirectly) of Health Care, Utilization Review, Medical Social Work or Administrative Services.--For the services listed, exclude from contracting any entity which employs, contracts with, or contracts through an entity which has been excluded from participation in Medicaid by the Secretary under the authority of §§1128 or 1128A of the Act.

D. Providing for Exclusion from Participation.--Require all organizations, as a part of the contracting process, to attest that all entities listed above are not involved with the organization in any of the above prohibited ways.

2087. HMO AND CERTAIN HIO CONTRACTS - GENERAL

2087.1 Prior Approval.--Unless one of the exceptions in subsection F applies, the prior approval requirements described in this section apply when you contract with an entity on a capitation or other risk basis to provide (or arrange for the provision of) comprehensive services as defined in §2085.1.

Unless one of the exceptions in subsection F applies, HCFA prior approval is a prerequisite for FFP. Prior approval is also required for amendments to such contracts. An amended contract is treated as a new contract. FFP in contract expenditures is available only if the RO has determined that the contract is (or was) approvable at the time the expenditures are (or were) incurred. Even if a contract receives approval, no FFP is available for services delivered at a time when an approvable written contract was not in place and effective.

ROs approve or disapprove such contracts and amendments. In order for a contract to be approved, the RO must be satisfied that it meets all applicable statutory and regulatory requirements. Submit all HMO and HIO contracts not mentioned in subsection F to the RO for review and approval prior to the proposed date upon which FFP is to begin. (This is usually the same as the proposed effective date of the contract.) Consult your RO to establish the time frame within which contracts or amendments must be submitted for prior approval. To expedite the approval process, submit draft or model contracts, at the direction of the RO, for preliminary review. (You are encouraged to work closely with your RO during the contract development process.) Once all negotiations with the HMO or HIO are finalized, submit a completed contract for RO approval. **All terms of the contract must be finalized. The RO cannot approve an incomplete contract.** FFP in costs incurred under a contract or amended contract is contingent upon the RO finding that the terms of the contract, in effect while costs are incurred, are approvable.

A. Examples of Prior Approval Situations.--

1. Contract Approval in Advance of Contract Effective Date.--If you submit a contract to the RO, and the RO determines that the contract meets all Federal requirements and approves the contract prior to the effective date of the contract, FFP is available for all costs incurred under the contract on or after the effective date.

2. Contract Approval Subsequent to Contract Effective Date.--If you find that, for whatever reason, you are not able to submit the contract to the RO prior to the effective date of the contract, no FFP is available prior to the RO determining that the contract is approvable. However, if the RO finds that: (1) the contract is approvable as submitted, and (2) that the terms of the approved contract were in effect for the contract period prior to the date that the RO finds the contract approvable, then FFP is available for costs incurred under the approved contract for the entire period for which an approvable written contract is (or was) effective and in place.

3. Contract Disapproval In Advance of Contract Effective Date.-- If you submit a contract to the RO prior to the proposed effective date of the contract, and the RO finds it incomplete or containing unapprovable terms, you must resubmit a contract which successfully addresses all of the RO concerns. If the second or later versions are submitted after the effective date of the contract, FFP is available **only** for costs incurred under the terms of a contract which the RO has found to be approvable. The RO determines the date on which the terms of the approved contract were in effect. There is no FFP for costs incurred prior to this date.

4. Contract Disapproval Subsequent to Contract Effective Date.--If you submit a contract to the RO for approval subsequent to the effective date of the contract, and the RO finds the contract to be either incomplete or containing unapprovable terms, there is no FFP for any costs incurred under such a contract. FFP is only provided for costs incurred under a new contract which is complete and fully addresses the problems cited by the RO. In this situation, there is no procedure for securing FFP in costs incurred under the prior contract. If subsequent contracts are also deemed by the RO to be either incomplete or unapprovable, FFP is unavailable until you submit a complete and satisfactory contract. Upon finding the contract approvable, the RO determines on which date the terms of the approved contract were in effect. FFP is only available for expenses incurred after the execution and effective date of an approvable written contract.

B. Prior Approval Policy and §1915(b) Waivers.--Whenever the terms of a contract with an HMO or HIO require a waiver authorized under §1915(b) of the Act, prior approval of such contracts is contingent upon your being granted a waiver for the contract period of performance.

C. Approvability of Contract Payment Rate Provisions.--The prior approval requirement limits the time available for contract negotiation between you and the contractor. In particular, the negotiation of rates is most affected by this time constraint. However, the RO may not approve a contract unless it contains:

- o The agreed upon rate or specific methodology (which does not include further negotiation) under which the payment rate is determined;
- o The actuarial basis for computation of the payment rates; and
- o Assurance that the contract payments do not exceed the fee-for-service upper payment limits (FFS-UPL) specified for risk contracts in 42 CFR 447.361.

In recognition of both the difficulty of the rate negotiation process and the need for prior approval of rates, the RO may approve the following contract provisions which, while consistent with the prior approval process described above, allow States flexibility in negotiating rates with HMOs and HIOs:

1. Expression of Payment Rate.--A contract may propose a payment rate expressed as any of the following:

- o A specified dollar amount, e.g., \$112 per member per month, as long as you express the FFS-UPL in the same terms;
- o A specified percentage of the FFS-UPL, e.g., 95 percent; or
- o An equation or algorithm, e.g., you and your contractor may have negotiated a methodology which is utilized to determine the dollar or percent of FFS payment rate. This methodology may be included in the contract as the payment rate as long as the implementation of the algorithm to produce the rate involves no further negotiation between you and your contractor.

2. Alternative Rates.--A contract may specify two alternative rates, with the selection of the one to be employed determined by terms specified in the contract. This may be useful if you are still computing the FFS-UPL while attempting to negotiate the contract. If you choose to utilize this option, the contract must specify that the rate is the higher/lower of a specified dollar amount or a specified percentage of the to be determined FFS-UPL, neither of which may exceed the FFS-UPL. When the FFS-UPL computation is completed, the rate is predetermined by the aforementioned contract specifications and is one of the two outcomes identified in the contract meeting the FFS-UPL requirements. A rate selected in this way may be effective on the effective date of the contract as long as the process for arriving at the rate is included as a term of the contract.

Since this approach specifies, prior to calculation of the FFS-UPL, the rate as the higher or lower of either a dollar amount or a percentage of the FFS-UPL, the rate is not subject to negotiation after the determination of the FFS-UPL. Any rate revisions based upon further negotiation are treated as contract amendments.

3. Rate Adjustments Based on More Recent Claims Data.--A contract which specifies the payment rate as a percent of the FFS-UPL may include a provision to adjust the actual payment amount during the period of performance of the contract as more recent claims data becomes available, which allows you to recalculate the FFS-UPL. Such a contract provision must specify how you make the FFS-UPL recalculation, when such changes are made, and when, during the contract period of performance, such changes are effective. Such a contract provision must also assure that resulting contract payments do not exceed the upper payment limits specified for risk contracts in 42 CFR 447.361.

These changes may be made retroactive to the beginning of the contract period. If such provisions are specified in the contract and approved by the RO, the resulting change in rates is not an amendment to the contract and does not need additional prior approval by the RO.

4. Contract Extension.--A contract may contain a provision which allows its period of performance to be extended automatically. This provides a transition period preceding the execution of a continuation contract between you and your existing contractor. Such a contract provision must specify the payment rate (using the options in subsection C) for the extension period. For example, the rate may be specified as the rate paid for the initial period of performance, or this rate plus an adjustment for inflation. The inflation adjustment amount must be specified in the initial contract and may not be negotiated after execution of this contract. Once the succeeding contract has received prior approval, it may be made effective on the same date as the beginning of the contract extension period, and the terms of the succeeding contract may supersede those governing the extension period. The original rate paid during the extension period is then superseded by the negotiated rate for the succeeding contract.

5. Multi-Year Contracts.--You may enter into a contract with an HMO or an HIO for a period of performance which is greater than 12 months, i.e., a multi year contract. A multi year contract may provide for rate changes at predetermined points in time. This option is most useful to a State which does not anticipate changing the terms of its contract (including rate setting methodology) from year to year, i.e., whose only change is recalculating the rate based on more recent FFS cost data and/or a predetermined inflation measure.

In order for these rate changes to receive prior approval at the time the RO approves the multi year contract, the contract must specify: (1) the conditions under which a rate change takes effect, (2) the methodology for determining the new rate (this determination may not involve future negotiation with the HMO or HIO), (3) the effective date for the new rates, and (4) that the new rates also meet the FFS-UPL requirement. If the multi year contract specifies these four items, the implementation of the rate change does not require prior approval. The change was approved with the original multi year contract.

Rate changes described in subsections 2, 3, 4, and 5, which have prior approval as part of the contract, must be submitted to the RO within 30 days of becoming effective. The RO then verifies that the rate change is only a fulfillment of changes allowed under the prior approved contract, not a new rate which was not provided for in the previously approved contract.

D. Approvability of Other Such Contract Provisions.--The contract provisions involving payment rates described in subsection C are optional. You may utilize other contracting provisions which offer equal or greater flexibility in the negotiation process. However, in order to adhere to the

prior approval requirement, all such contract provisions which propose changes to the terms of the contract during the period of performance of the contract must:

- o Describe the anticipated change, e.g., a change in the scope of services;
- o Describe the process (which may not involve negotiation with the contractor) which determines the qualitative and quantitative character of the change, including:
 - rationale, methods and conditions under which such changes are made,
 - when the changes are made, and
 - when the changes are effective; and
- o Not require further negotiation between you and the contractor.

E. State Claims for FFP.--Upon negotiation of the contract, immediately forward a copy of the contract to your RO for review and approval.

FFP for these contracts is budgeted for on line 17.E of Form HCFA-25 and claimed on line 17.E of Form HCFA-64. See §§2500.2 and 2601 for instructions. Do not submit any claims for FFP in payments made under the contract until you have received notification from the RO that the contract is approved for FFP. Once the contract is approved, claims must not include costs incurred under the contract for any period of time during which the contract was not approvable. The RO informs you of the date upon which FFP is available for costs incurred under the approved contract.

F. Types of Comprehensive Risk Contracts Not Subject to Prior Approval.--The following types of comprehensive risk contracts are exempt from the prior approval requirements:

- o Contracts for less than \$100,000,
- o Contracts with entities described in §1903(m)(2)(B) of the Act,
- o Contracts with HIOs that became operational prior to January 1, 1986, and
- o Demonstration contracts under which §1903(m)(2)(A) requirements are waived, and no prior approval requirement is imposed as a term or condition of the demonstration.

2087.2 Sound Procurement Process With Competitive Bidding or Noncompetitive Negotiation.--In general, HMO contracts are obtained through a competitive bidding process. Use sealed bids or competitive negotiation to obtain your HMO contracts. However, in certain circumstances, the RO may suspend this competitive bidding requirement and employ noncompetitive negotiation for procurement.

45 CFR 74 (Appendix G, paragraph 11.d.) lists the following circumstances under which a contract may be awarded by noncompetitive negotiation:

- o The item is available only from a single source;

- o In the event of public exigency or emergency when the urgency for the requirement does not permit a delay incident to competitive solicitation;
- o The Federal grantor agency authorizes noncompetitive negotiation; or
- o After solicitation of a number of sources, competition is determined inadequate.

Suspension of competitive procurement is appropriate when there is only one HMO in the service area or when the State demonstrates a willingness to contract with any interested HMO which meets the required criteria. Evidence must be offered to the RO that competitive procurement has been used and proved to be inadequate or infeasible, or that it is not appropriate to use competitive procurement given the local situation. If the RO believes competitive procurement must not be suspended, then HMO contracts must be competitively bid.

2087.3 Termination of Contract With HMO.--You must include in your contract criteria for termination of the contract by either you or the contractor and procedures to be followed in the event of termination, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding Medicaid claims. (See 42 CFR 434.6(6).)

Further, the contract must specify conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor. (See 45 CFR 74, Appendix G.)

2087.4 Subcontracts.--In a subcontract, the HMO contracts or delegates some of its management functions or responsibilities for providing medical care to its enrollees to another entity. The HMO may subcontract any of the functions it performs under its contract with you. Your contract with the HMO must specify which functions may be subcontracted.

All subcontracts must be in writing. No subcontract terminates the legal responsibility of the contractor to you to assure that all activities under the contract are carried out. The HMO is not relieved of its contractual responsibility to you by shifting that responsibility to a subcontractor.

In addition, subcontracts must meet the regulatory requirements governing contracts with HMOs (see 42 CFR 434) that are appropriate to the service or activity being delegated. For instance, it is appropriate for the subcontract to contain provisions allowing you and DHHS to evaluate through inspection or other means, the quality, appropriateness and timeliness of services (see 42 CFR 434.6(a)(5)) performed under a subcontract to provide medical services. It is also appropriate for such a subcontract to contain provisions pertaining to maintenance of an appropriate record system for services to enrolled recipients. (See 42 CFR 434.6(a)(7).) As set forth in §2086.8, the composition of enrollment requirement (see 42 CFR 434.20) is not appropriately applied to subcontractors. You and the RO must use your judgment as to the requirements that appropriately apply to each type of subcontract. Procurement of subcontractors by the contractor is to be performed in accordance with the instructions for a sound procurement process described in §2087.2. Assure that each subcontract contains sufficient provisions to safeguard all rights of enrollees and that the subcontract complies with all applicable State and Federal laws.

2087.5 Disclosure of Information on Ownership and Control.--Have all HMOs and HIOs supply to you, as a requirement of your contract with them, full and

complete information as to the identity of each person or corporation with an ownership or control interest in the HMO or HMO, or any subcontractor in which the HMO or HMO has a 5% or more ownership interest. This information, which can be submitted as a document separate from the contract, is a necessary condition for RO approval of the contract between you and the HMO or HMO. (See §1903(m)(2)(A)(viii) of the Act and 42 CFR 455.100 - 455.104.)

A. Definition of "Person With an Ownership or Control Interest".--A "person with an ownership or control interest" means a person or corporation that:

- o Owns, directly or indirectly, 5% or more of the HMO's or HMO's capital or stock or receives 5% or more of its profits (see subsection B);
- o Has an interest in any mortgage, deed of trust, note, or other obligation secured in whole or in part by the HMO or by its property or assets, and that interest is equal to or exceeds 5% of the total property and assets of the HMO or HMO; or
- o Is an officer or director of the HMO or HMO (if it is organized as a corporation) or is a partner in the HMO (if it is organized as a partnership).

B. Calculation of 5% Ownership or Receipt of Profits.--The percentage of direct ownership or control is calculated by multiplying the percent of interest which a person owns by the percent of the HMO's assets used to secure the obligation. Thus, if a person owns 10 percent of a note secured by 60 percent of the HMO's assets, the person owns 6% of the HMO.

The percentage of indirect ownership or control is calculated by multiplying the percentages of ownership in each organization. Thus, if a person owns 10 percent of the stock in a corporation which owns 80 percent of the stock of the HMO, the person owns 8% of the HMO.

C. Information to be Disclosed.--The following information must be disclosed to you:

- o The name and address of each person with an ownership or controlling interest of 5% or more in the HMO or HMO or in any subcontractor in which the HMO or HMO has direct or indirect ownership of 5% or more;
- o A statement as to whether any of the persons with ownership or control interest is related to any other of the persons with ownership or control interest as spouse, parent, child, or sibling; and
- o The name of any other organization in which the person also has ownership or control interest. This is required to the extent that the HMO can obtain this information by requesting it in writing. The HMO must keep copies of all of these requests and responses to them, make them available upon request, and advise you when there is no response to a request.

D. Potential Sources of Disclosure Information.--This information may already have been reported on Form HCFA-1513, "Disclosure of Ownership and Control Interest Statement." Form HCFA-1513 is likely to have been completed in two different cases. First, if an HMO is Federally qualified and has a Medicare contract, it is required to file Form HCFA-1513 with HCFA within 120 days of the HMO's fiscal year end. Secondly, if the HMO is owned by or has subcontracts with Medicaid providers which are reviewed by the State survey

agency, these providers may have completed Form HCFA-1513 as part of the survey process. If Form HCFA-1513 has not been completed, the HMO may supply the ownership and control information on a separate report or submit reports filed with your State's insurance or health regulators as long as these reports provide the necessary information for the prior 12 month period.

As directed by your RO, you must provide documentation of this disclosure information as part of the prior approval process for contracts. This documentation must be submitted to you and the RO prior to each contract period. If an HMO has not supplied the information that must be disclosed, a contract with the HMO is not considered approvable for this period of time and no FFP is available for the period of time preceding the disclosure.

2087.6 Disclosure of Information on Business Transactions - State Plan Defined HMOs.--All HMOs which are not Federally qualified must disclose to you information on certain types of transactions they have with a "party in interest" as defined in the Public Health Service Act. (See §§1903(m)(2)(A)(viii) and 1903(m)(4) of the Act.) This requirement must be contained in your contract with the HMO or HIO as a precondition for approval by the RO for receiving FFP. Federally qualified HMOs already report this information to HCFA. The law exempts them from reporting it again to you.

A. Definition of A Party in Interest.--As defined in §1318(b) of the Public Health Service Act, a party in interest is:

1. Any director, officer, partner, or employee responsible for management or administration of an HMO and HIO; any person who is directly or indirectly the beneficial owner of more than 5% of the equity of the HMO; any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5% of the HMO; or, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

2. Any organization in which a person described in subsection 1 is director, officer or partner; has directly or indirectly a beneficial interest of more than 5% of the equity of the HMO; or has a mortgage, deed of trust, note, or other interest valuing more than 5% of the assets of the HMO;

3. Any person directly or indirectly controlling, controlled by, or under common control with a HMO; or

4. Any spouse, child, or parent of an individual described in subsections 1, 2, or 3.

B. Types of Transactions Which Must Be Disclosed.-- Business transactions which must be disclosed include:

o Any sale, exchange or lease of any property between the HMO and a party in interest;

o Any lending of money or other extension of credit between the HMO and a party in interest; and

o Any furnishing for consideration of goods, services (including management services) or facilities between the HMO and the party in interest. This does not include salaries paid to employees for services provided in the normal course of their employment.

The information which must be disclosed in the transactions listed in subsection B between an HMO and a party in interest includes:

- o The name of the party in interest for each transaction;
- o A description of each transaction and the quantity or units involved;
- o The accrued dollar value of each transaction during the fiscal year; and
- o Justification of the reasonableness of each transaction.

You may require that the information on business transactions be accompanied by a consolidated financial statement for the HMO and the party in interest.

Your contracts with HMOs must contain a provision requiring the reporting of this information to you. If the contract is being renewed or extended, the HMO must disclose information on business transactions which occurred during the prior contract period. If the contract is an initial contract with Medicaid, but the HMO has operated previously in the commercial or Medicare markets, information on business transactions for the entire year preceding the initial contract period must be disclosed. The business transactions which must be reported are not limited to transactions related to serving the Medicaid enrollment. All of the HMO's business transactions must be reported.

2087.7 Audit and Inspection Rights.--The contract must give you and HCFA certain audit rights. Include in all contracts provisions which allow you and HCFA access to any books, documents, papers, and records of the contractor which are directly pertinent to that specific contract, for the purpose of making an audit, examination, excerpts, and transcriptions. This includes audit and inspection authority for a State authority and HCFA of any books and records of the HMO (and of any subcontractor) that pertain (1) to the ability of the entity to bear the risk of financial losses or (2) to services performed or determinations of amounts payable under the contract. (See §1903(m)(2)(A)(iv) of the Act.)

2087.8 Encounter Data.--HMOs must maintain sufficient patient encounter data to identify the physician who delivers services to Medicaid patients. (See §1903(m)(2)(A)(ii) of the Act.) You must include a provision to this effect in contracts established after the systems for unique physician identifiers (see §1902(x) of the Act) are in place.

2088. ENROLLEES AND BENEFITS

2088.1 Potential Enrollees.--The contract must identify the types of Medicaid recipients whom the HMO can enroll. The HMO must agree to enroll these persons in the order in which they apply. The contract may stipulate a maximum number of Medicaid recipients who may be enrolled at any one time and that the HMO must enroll less than 75 percent Medicare and Medicaid enrollees. (See §§2086.8 through 2086.14.)

2088.2 Limiting Enrollment to Eligibility Categories.--The HMO may limit enrollment to a single eligibility category or combination of categories such as AFDC or SSI recipients, optional categorically needy or medically needy recipients. Or, the HMO may be required to enroll all categories of eligibles.

2088.3 HMOs for Specific Health Needs.--As set forth in §2090.4, HMOs are prohibited from restricting enrollment (and from disenrolling) based upon the expectation that an applicant or enrollee will require frequent or high cost

care. The HMO may target enrollment to subcategories such as pregnant women, the mentally ill or AIDS patients. Targeting specific groups is permissible as long it does not have the effect of screening out higher risk Medicaid recipients who might be expected to utilize health care services at a higher than average level or who appear likely to require more expensive health care services. HMOs designed to serve the needs of the previously cited subcategories actually target populations expected to utilize health care services at a higher than average level. Some states have rate structures for clients with special needs. If you anticipate developing an HMO of this type in your State, contact HCFA for assistance.

2088.4 Services Which HMO Provides.--The contract must specify the amount, duration and scope of the medical services which the HMO provides. Any service normally available under Medicaid not covered by the HMO must be available to the recipient under FFS.

Substantive changes may occur under FFS during a contract year. Address provisions for such changes in an HMO contract which defines benefits that must be offered in terms of the services provided. For instance, if the HMO is to offer all drugs included in the Medicaid formulary and an expensive new drug is added to the formulary, this may be handled several ways. The contract may be written to require the HMO to (1) absorb the cost of additional services, (2) provide additional service with an adjustment to its capitation rate, or (3) provide the additional services and receive an FFS payment rate.

The HMO may provide services in addition to those available in the State Plan. You and the HMO decide what, if any, additional services are offered. As long as your payments to the HMO for providing Medicaid covered services do not exceed the cost you would incur in providing those services (see §2089.3), you are entitled to FFP in the full amount of such payment even if the HMO is required under its contract to provide additional services for no additional payment. In other words, if the additional service is part of the total package of benefits, and the total HMO payment is under the FFS-UPL for the Medicaid covered services, it is permissible. (See 42 CFR 434.6(a)(4) and 447.361.)

2088.5 Freedom of Choice for Family Planning Services.--Sections 1902(a)(23)(B) and 1905(a)(4)(C) of the Act and 42 CFR 431.51(b) require that a person's enrollment in an HMO does not restrict the choice of the provider from whom the person may receive family planning services and supplies. You must cover family planning supplies and services provided by any qualified provider, even though the individual is enrolled in an HMO and the provider does not contract with the HMO. This means that the recipient may obtain family planning services and supplies from outside of the HMO without an HMO referral, even if the HMO contracts with Medicaid to provide the same services. For the family planning services and supplies provided outside the HMO, you have three options. You may hold the HMO responsible for covering such services by making FFS payments to non-plan providers. You may cover out-of-plan services while the HMO covers in-plan services. Or, you may cover all family planning services directly on a FFS basis. In all three cases, adjust the HMO's capitation payments accordingly.

Through a revision created by OBRA 1987, States are allowed to guarantee up to six months of eligibility in certain HMOs. If the HMO contracts to provide family planning services and supplies, the guaranteed eligibility provision allows the HMO enrollee to continue to receive family planning services and supplies from providers outside the HMO.

2088.6 Recipient Access to Federally Qualified Health Center (FQHC) Services.--You must make FQHC services available to all recipients. However, the following conditions apply to this general statement:

- o Where recipients voluntarily enroll in an HMO or a primary care provider in a §1915(b) waiver program, they have exercised their right not to choose FQHC services as a result of their decision to enroll. Thus they are not entitled to obtain FQHC services outside of the structure of their HMO or primary care provider. They may elect to disenroll in order to regain access to an FQHC.

- o Where a recipient is in a mandatory §1915(b) waiver program with a choice between several HMOs, PHPs, FFS primary care case management programs (FFS-PCCMs), or PCCMs in an HMO setting, the requirement for you to make FQHC services available has been met as long as:

- FQHCs are available to the recipient as either a contracting entity or case manager;
- Enrollment at the FQHC source is accessible (within accepted community standards for distance and travel times) and not at or over capacity; and
- The recipient has made a choice to enroll with one of the non-FQHC contractors or case managers.

- o Where the recipient did not have the opportunity to enroll with an FQHC as a primary care contractor or case manager, then he/she must be able to gain access to FQHC services outside of the waiver, and you must pay for these services. However, you may require that all FQHC services be coordinated through the case manager to assure proper management of all care being provided.

You need not contract or have agreements with all available FQHCs in order to guarantee availability of these services. Rather, you must contract or have agreements only with sufficient numbers so that the recipient choice remains available, i.e., that participating FQHCs located within accepted community standards for distance and travel time are not filled to capacity.

As long as there is at least one FQHC available to recipients as a case manager in a managed care setting, you cannot be required to contract with others nor are you required to pay for FQHC services provided by other FQHC providers for enrollees who had the opportunity to choose this type of provider as a case manager initially. However, this does not prohibit a plan affiliated case manager from referring his or her enrollees to an FQHC for a particular service.

2088.7 HMO Must be Able to Provide Services in Contract.--The HMO may provide services directly or may arrange for services to be provided by subcontractors. The HMO contract must specify which functions may be subcontracted with providers and show that it is able to provide adequate services directly or through its subcontracts. (See 42 CFR 434.50(b) and 434.52.)

2088.8 State Must Provide Services Not Offered by HMO.--The HMO contract must be very specific about the exact services which the HMO provides since you must provide under the FFS program all benefits in the State Plan not offered by the HMO. (See 42 CFR 434.65.)

2089. CAPITATION PAYMENTS

2089.1 Contract Must Specify Capitation Payment Amounts.--You determine the capitation rates to be paid to the HMO. These costs may not exceed the cost you would have paid under FFS for the same services to the same population.

You may use a competitive bidding process to establish the rates you pay. You may negotiate the payment rate with the HMO using the HMO's estimated costs of providing care. As long as you do not retroactively adjust payments to cover the HMO's cost of actually providing services, it remains a risk contract. The contract must specify the capitation payments.

2089.2 Actuarially Sound Payments.--As part of the prior approval process, the RO must find that your capitation fees and any other payments provided for in the contract are computed on an actuarially sound basis. (See §1903(m)(2)(iii) of the Act.) The contract (or supporting documentation which is incorporated by reference in the contract) must describe the actuarial basis and the methodology used to compute the capitation rates. (See 42 CFR 434.23.) It must also specify that the fees and any other payments provided for in the contract do not exceed the payment limits set forth in 42 CFR 447.361.

In developing a payment methodology, you may consult with the RO. Once you have made your determination as to what methodology to use, HCFA reviews the methodology. To expedite this part of the prior approval process, you may want to develop a standard capitation methodology for use in all of your contracts. The RO then reviews the methodology in depth only one time. When the methodology is used in other HMO contracts or in subsequent contracts, the RO verifies that the methodology accommodates recent coverage and reimbursement changes in the FFS environment and that the basis for data collection of FFS costs has not changed.

2089.3 Payment Cannot Exceed Fee-for-Service Upper Limit.--The total amount paid to the HMO cannot exceed the upper payment limit of what it would have cost you to provide these same services under FFS to an actuarially equivalent population. This includes payments for which FFP is requested as well as those for which it is not requested. (See 42 CFR 434.23(b) and 434.361.)

Incentive payments or bonuses for agreeing to enter into a risk contract are permitted under the following conditions:

1. They must be made as a reward for signing a valid and binding contract and accordingly cannot be affected by the HMO's actual performance or non-performance or any aspect of the contract itself.

2. Since the payment is not made for providing services, the amount of the payment may not vary based upon the cost of providing services in the area served by the HMO.

3. This payment is made to any HMO that signs or renews a risk contract with the State as an incentive to do so.

FFP is not available for these incentive payments or bonuses. The payment is considered neither a Medicaid payment nor a payment for providing services or carrying out contract provisions. It is made solely pursuant to State rather than Federal authority.

2089.4 Hospital and NF Payment Rates.--You have the option of requiring hospitals and NFs to accept the FFS payment rate as payment in full from a risk based Medicaid contracting HMO. (See 42 CFR 447.15.) You may guarantee the

FFS hospital or NF rate to the HMO if the provider participates in Medicaid. If you choose to exercise this option, you may wish to take this into consideration when determining capitation payments. You may wish to specify this as a requisite for the institutional provider to become a participating provider. Some States presently apply this policy. You must determine whether your State requires legislation in order to accomplish this.

2089.5 Capitation Rate Changes.--The period of time to be used as the basis for making the comparison between FFS and capitation rates is the most recent period of time prior to the contract approval date for which adequate FFS data is available for use in establishing capitation rates. If the prior approval process determines that adequate FFS data has been used in making the comparison, and if capitation rates at the beginning of the contract period do not exceed the most accurate FFS rates available for this period, a contract is determined to be in compliance with the FFS-UPLs for the duration of the contract period (not to exceed 12 months) as long as there is no change in capitation rates. If you establish a multi-period contract which exceeds 12 months in duration, the comparative determination that the capitated rates do not exceed FFS rates must be made at least every 12 months.

HCFA allows rate changes (regardless of whether they are reductions or augmentations) and provides FFP in such changes as long as the changes are implemented through either a formal contract amendment or a multi-period contract and continue to meet all applicable statute provisions and regulations. If rate changes are implemented through a contract amendment, the amendment must receive prior approval by the RO before FFP in any higher payment amounts may be awarded. If the rate change is an anticipated development in a multi-year process, it must also be reviewed by the RO, consistent with guidelines for multi-year contracts.

2089.6 Rate Setting for Specific Health Needs.--A stop-loss provision in the contract between you and the HMO may provide an acceptable option for you to limit the HMO's financial liability for any enrollee who exceeds a certain level of costs in a certain period. For instance, you may allow the HMO to bill under FFS for all of an enrollee's costs which exceed some dollar threshold, such as \$20,000 per year. In that case, the FFS-UPL must be adjusted downward to remove those expenditures which are over \$20,000 per person per year from the base expenditures.

Such a stop-loss provision could be used to limit the outer bounds of the HMO's liability in high cost medical conditions or illnesses. In the managed care and insurance industries, stop-loss provisions are generally used to limit the HMO's financial liability in cases involving extraordinary and unanticipated expenses, and stop-loss caps are generally set at a high level that is rarely reached. But most disease-specific high cost cases exceed whatever stop-loss caps you might set, so stop-loss could delimit the financial liability of the HMO for specific diagnoses.

Another option is to negotiate a special, i.e., higher, capitation rate to be paid to HMOs for members who are diagnosed as having a high cost medical condition. You may also develop an alternative payment methodology and have the contract specify, for instance, that the HMO be reimbursed on a FFS basis for its specified enrollees. Either of these options reimburses the HMO fully for treating a person from the time the disease is diagnosed.

2089.7 Collection of Third Party Liability Payments.--Take into account third party liability recoveries in the capitation rate setting methodology. When you estimate the FFS-UPL, reduce it by the amount of all third party reimbursements received for these services. Thus, the upper limit on your

payment to the HMO is net of third party collections. You can then allow the HMO to retain any third party recoveries which it is able to collect on behalf of its Medicaid enrollees.

2089.8 Copayments, Coinsurance and Deductibles.--Copayments, coinsurance and deductibles cannot be charged for services furnished by an HMO to categorically needy individuals. If your State Plan provides for the imposition of cost sharing on medically needy recipients, however, and does not exclude HMO enrollees from such cost sharing obligations pursuant to 42 CFR 447(b)(6), HMOs may impose on medically needy enrollees the same cost sharing obligations imposed on FFS recipients. Regardless of whether an HMO imposes such cost sharing, calculate payments to the HMO on the assumption that these amounts are collected. (See 42 CFR 434.20(e)(3) and 447.50 - 447.58.)

2089.9 FQHC Reimbursement.--FQHCs must be paid their reasonable costs on demand (as specified by §1902(a)(13)(E) of the Act) when an FQHC provides Medicaid covered services without a contract. In the context of contracting, FQHCs must be paid their reasonable costs when (1) the FQHC has demanded such reimbursement as a contract term and (2) you or the Medicaid contracting HMO elects to contract or subcontract with the FQHC.

You may reimburse FQHCs at rates other than those specified in §1902(a)(13)(E) of the Act if that reimbursement rate or methodology (e.g., capitation, global fees) is agreed upon by the FQHC. For example, an FQHC may wish to agree to a particular capitation rate if acceptance of that rate is a condition for contracting as a primary care case manager under a §1915(b) waiver program.

When an HMO with a comprehensive risk contract subcontracts with an FQHC, your payments to the HMO must reflect payment rates under §1902(a)(13)(E) of the Act. The HMO has the right to elect to be paid at these rates for the services described in §1905(a)(2)(C) of the Act.

An FQHC may contract directly with you as an HMO on a negotiated risk capitation basis or may assert its right to reasonable cost reimbursement and contract as a PHP pursuant to the regulations applicable to non-risk contracts with PHPs. Under such PHP contracts, the FQHC must fully comply with your payment and billing systems and provide you with all cost reporting information required by you to verify reasonable costs and apply applicable reasonable cost reimbursement principles.

You are under no obligation to pay an FQHC its reasonable costs as set forth in §1902(a)(13)(E) of the Act in the following situations:

- o The FQHC has not demanded such reasonable cost reimbursement;
- o The FQHC fails to comply with your payment and billing systems, including a failure to provide cost reporting information in the format required in order for you to apply applicable reasonable cost principles; or
- o The FQHC subcontracts to an HMO. In such a case, the subcontract is not reimbursable using reasonable cost methodologies under §1902(a)(13)(E) of the Act, although the FQHC itself might be providing some services directly which qualify for reasonable cost reimbursement.

2090. MARKETING, ENROLLMENT AND DISENROLLMENT

2090.1 Marketing Materials and Plans.--The contract must specify the methods by which the HMO will assure you that marketing plans, procedures, and materials are accurate, and do not mislead, confuse or defraud either you or the recipients. (See 42 CFR 434.36.)